SPECIFICATION RISK ANALYSIS:
AVOIDING PRODUCT PERFORMANCE DEVIATIONS THROUGH AN FMEA-BASED METHOD

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ABSTRACT

This thesis investigates the potential application of the Failure Mode and Effect Analysis (FMEA) as a method that facilitates risk management for product architectures.

The process described by Pahl & Beitz and the Munich Procedural Model form the guiding frameworks to describe the process of product development in this thesis. Additionally, the perspective of Lean Product Development is taken into account.

Risks in the phase of value creation in general, and in the phase of embodiment design in particular, are identified and described. Risk Management is analyzed and existing frameworks in product development, project management, and supply chain management are compared and analyzed. The Failure Mode and Effect Analysis is discussed and its current application is presented. It is compared to the risk management frameworks and its potential application as a tool for risk management is investigated.

In the Embodiment Design phase, the product architecture is elaborated. This is achieved by transforming the working principle into a physical layout according to the product specifications. The achievement of those is crucial for the later success of the product. Thus, the characteristics of this design phase are analyzed from a perspective of risk management. Twenty-four requirements for a method to manage the risk of not achieving specifications are derived.

Based on these requirements, a risk management tool named Specification Risk Analysis was developed. The method follows the procedure of the FMEA and identifies, assesses, and ranks product specifications that are challenging to achieve. It avoids product deficiencies and provides a systematic approach to develop appropriate mitigation measures. Thus, the method seeks to prevent time and cost-consuming changes at a later point.

The method was continuously improved by means of interviews, a pilot test, and a field study. The field study was conducted with teams from a product design course at MIT. Its objective were the application and improvement of the Specification Risk Analysis, as well as assistance for the teams regarding their key challenges. Additionally, the field study helped to evaluate the method under the perspective of value creation. Findings from the field study confirmed the benefits the method seeks to achieve.

To Lily and Jim

Hope is not the conviction that something will turn out all right.
Hope is the certainty that something has a deeper meaning, no matter how it will turn out.

Václav Havel

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1 Introduction

This chapter gives a first introduction to the reader. The motivation behind this thesis is described in section 1.1. Three research questions are derived and characterized in section 1.2. In section 1.3, the scope of this thesis and its research methodology are presented. Finally, the outline of the thesis is described in section 1.4.

1.1 Motivation

Traditionally, the trade-off between time, cost and quality has been considered as a dilemma in product development [LINDEMANN 2006A]. The received opinion was that no optimal results regarding all three dimensions could be achieved at one point.

The tension between time and quality was seen, in simple terms, as the following: the more time spent, the better product quality can be achieved. However, a conflictive goal is to develop a product within little time in order to minimize the time to market. And, of course, to minimize costs. The third dimension costs adds a further tension to this trade-off. Adding resources (e.g. financial means or manpower) to the development process may reduce the development time and may help to achieve better quality, but as a consequence development costs increase. The interdependence between the three dimensions has become known as the dilemma in product development. In the past, companies sought to achieve the right tradeoff in order to maximize their profits.

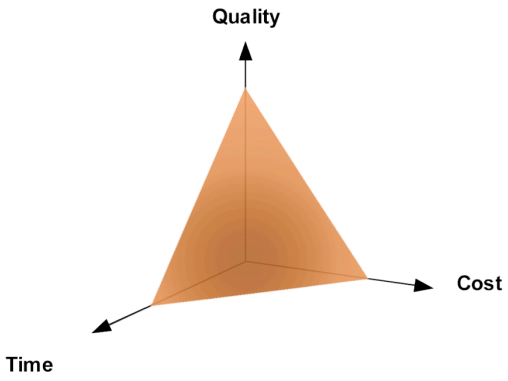


Figure 1-1: Dilemma in Product Development

Lean Product Development (LPD) has presented a new approach to manage the conflict between time, cost, and quality. Elaborated at the Toyota Motor Company over years, the approach proved that a company can build high-quality cars at low costs. Now, achieving high quality no longer implicates the need of large funds or resources.

Lean Product Development seeks to address all three dimensions of the former dilemma. High quality can be achieved at a level of low cost by eliminating waste in all relevant resources and activities. Furthermore, Lean Product Development seeks to achieve the objectives within little time. By means of the philosophy, the challenge of developing a product at low costs and within little time can be mastered, e.g. by concentrating on value creation and minimizing non-value adding activities to the extent possible.

Risk or uncertainty adds a forth dimension that is difficult to understand and address [ESD 2004, p. 20]. According to BROWNING ET AL. [2002], risk is a qualifier on schedule (time), cost, and performance (quality). Effectively managing risk in new product development significantly reduces the likelihood of cost, schedule, and performance deviations during execution. Risk management therefore is tightly connected to the success of a product development process and addresses all three dimensions.

Risk management and the dimension time are tightly connected. Of course, its execution takes up some time. However, since risk management seeks to identify potential threats and to prevent late changes, time-consuming iterations loops and redesign may be prevented. Additionally, risk management achieves similar benefits regarding the objectives of costs. Although funds are needed for the implementation and execution of risk management, significant savings may be achieved by early identification of risks and prevention of potential late changes in the process. Finally, risk management also addresses the third dimension quality. Those two areas are probably the most similar ones and should have some significant parallels. Both focus on potential errors and seek to minimize the occurrence of them.

Many risks inherent in a product are defined with its architecture. The architecture of a product is elaborated in the embodiment design phase in product development. Numerous aspects are not defined until then and the phase is crucial for later success of the product. A survey conducted in the automotive industry pointed out that the final state of a product is determined by how successfully the requirements have been incorporated into a design solution. But the survey also showed that a perfect requirements specification does not guarantee a perfect product, and requirements are often not fulfilled throughout a solution [ALMEFELT ET AL. 2006].

Managing product development processes thus requires a reliable method for assessing the risks and challenges of the product to develop. Unfortunately, only a very limited number of work methods exist which facilitate this. This leads to uncertainty in evaluating different concepts, in assigning resources to the development process, and in assessing the future market potential of the product. Thus, a practical method is needed that manages risks regarding product specifications, and addresses all dimensions of product development.

A well established method for assessing risks regarding the quality of products and production processes is the Failure Mode and Effect Analysis (FMEA). It helps to focus on core challenges while still including a wide range of risks. Since the nature of risks and quality issues is very similar, the general idea and framework of an FMEA may possibly be adapted successfully to embodiment design.

1.2 Research Questions

The objectives this thesis seeks to achieve can be expressed by means of three research questions, which are presented below.

Because of the nature of inventions and innovations, product development has to deal with a various number of uncertainties. However, it is crucial to know what the uncertainties are in order to address and manage them successfully. Therefore, a brief overview should be given *what risks may occur in the phase of value creation in general? What are risks associated with embodiment design?*

The phase of embodiment design will be a focus of this thesis. A various number of aspects are determined in this phase and important decisions with extensive consequences are made. Among others, dimensions, materials, and the arrangement of the later product's subsystems are specified. Risk management seeks to reduce the likelihood of deviations regarding the objectives the product should achieve. It has the potential to identify possible threats early in the process and minimize undesired occurrences. Thus, it is important to know *what are the characteristics of embodiment design? What are the fundamental principles of risk management in order to prevent performance deviation in this phase of product development?*

This thesis intends to develop a method to assess and manage risks of the product architecture. The architecture is elaborated during the embodiment design phase and seeks to comply with the requirements, expressed as product specifications. The fulfillment of them is crucial for the later success of a product. Thus, it is important to identify the specific needs the method has to fulfill. Insights will be derived from the analytical method FMEA, which forms the initial fundament for the method to develop. The question needs to be answered *what are the requirements regarding a method to manage risk of not achieving product specifications that is based on the FMEA and suitable for embodiment design. How does the method look like?*

1.3 Scope of the Thesis and Research Methodology

Driven by the motivation and the research questions presented in the previous sections, this thesis investigates a method to assess and manage risks during the embodiment design phase. Therefore, this thesis discusses three initial aspects (see Figure 1-2): (a) the fundamentals of risk management, (b) the Failure Mode and Effect Analysis (FMEA) as an analytical tool, and (c) the characteristics of the embodiment design phase.

Furthermore, this research compares the FMEA and risk management regarding similarities and differences. It is investigated whether the FMEA method can be applied to embodiment design in order to manage risk of not achieving product specifications. The scope of this thesis is limited to the phase of embodiment design and does not investigate a potential application in other phases of product development.

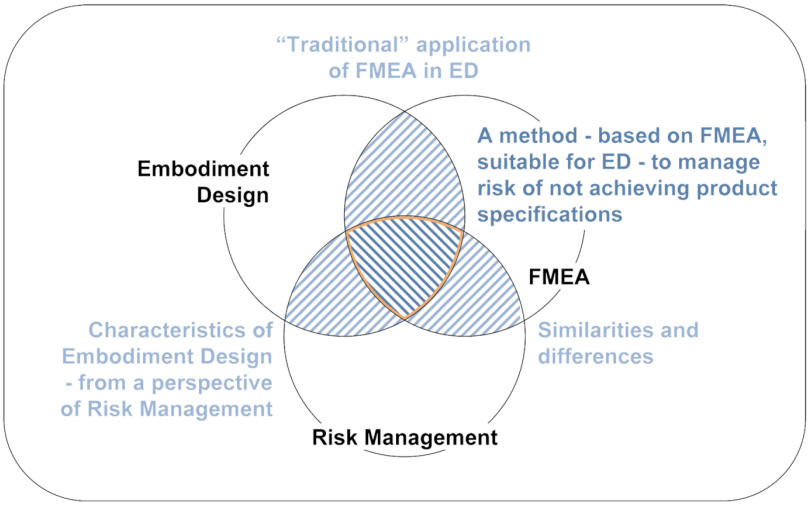


Figure 1-2: Scope of the Thesis

The research uses a combination of surveys, interviews, structured methods, and direct observation for data collection. As a starting point, previous theses in the field of Lean Product Development were studied to identify current fields of interest. Interviews with professors and researchers in the fields of product development and supply chain management were conducted at MIT. A literature review rounds off the analysis of the state of the art.

Based on the gained knowledge, and after several iterations, a first draft to address and manage specification risks in embodiment design is developed. A small pilot test is carried out within the Lean Product Development group of MIT's Engineering Systems Division. Based on the gained feedback, the method is refined and further elaborated. It is applied in a field study with several teams of a product design course at MIT. Observing the application and conducting surveys within the participants identifies the effectiveness of the method and further room for improvement. Within an iterative and continuous improvement process, the insights are incorporated into the method until its current state is achieved.

1.4 Thesis Outline

The first chapter introduces the reader to the motivation behind this thesis (section 1.1). Three research questions are derived and presented in section 1.2. Additionally, its scope and research methodology are described (section 1.3).

Chapter 2 establishes a common language. The product development process described by PAHL & BEITZ [2006] is presented and connected to the more flexible approach of the Munich Procedural Model (section 2.1). Afterwards, the fundamentals of Lean Product Development are described (section 2.2). In section 2.3, potential risks in product development are presented from a perspective of value creation in general to embodiment design in particular.

Chapter 3 analyzes the state of the art. First, the fundamentals of Risk Management are presented in section 3.1. The FMEA is described and its similarities to Risk Management are investigated (section 3.2). Finally, Embodiment Design is discussed in section 3.3. An interim summary about the potential of the FMEA as a risk management tool completes this chapter (section 3.4). Throughout this chapter, requirements for the method to develop are derived.

The development of the Specification Risk Analysis is presented in chapter 4. The derived requirements are briefly summarized in section 4.1. Potential focuses of the method are discussed and the decision is made to concentrate on product performance aspects (section 4.2). Section 4.3 briefly describes the procedure of the development. The most profound change in the FMEA, the derivation of the assessment categories and scales, is presented in more detail in section 4.4. The incorporation of the remaining requirements is described in section 4.5. The chapter is rounded off by a brief summary (section 4.6).

Chapter 5 presents the final version of the Specification Risk Analysis. Its point of application as well as the objectives the method seeks to achieve are described in section 5.1. The individual steps of the method are specified in section 5.2. Section 5.3 presents the effects that can be achieved by the application of the method. At the end of this chapter, an overview of the Specification Risk Analysis is given in form of a table (section 5.4).

The pilot test and the field study, which is conducted with teams from a course at MIT, are presented in chapter 6. At the beginning, the objectives, research methodology, and execution of the field study are described in section 6.1. Afterwards, the gained data is analyzed (section 6.2). Section 6.3 presents the feedback the participants provided. A generic conclusion and a reflection about the field study and the method itself round off this chapter (section 6.4, section 6.5).

Chapter 7 reviews the procedure and presents an outlook. First of all, section 7.1 analyzes the Specifications Risk Analysis from a perspective of Lean Product Development. Possible future directions for research are described in section 7.2. At the end, a personal reflection is drawn (section 7.3).

The last chapter presents a brief summary of the thesis (chapter 8).

2 General Context

At the beginning, the underlying frameworks in product development for this thesis are presented. Chapter 2 intends to establish a common language for the reader. The terms of PAHL & BEITZ [2006] are introduced, as well as the Munich Procedural Model in order to describe the process of product development (section 2.1). Furthermore, this thesis intends to consider the process of product development from a perspective of Lean Product Development. The philosophy and its principles are briefly characterized in section 2.2. In the last section, the chapter defines the perception of risk in this thesis. It will discuss risks that may occur in the phase of value creation - from a general point of view to embodiment design in particular (section 2.3).

2.1 Phases of Product Development

Successful products are crucial for a prospering economy. Products are only successful if they provide what the customer values and demands while manufacturing is economically reasonable. No matter if they are technical products, natural products, or services, they form the basis for trade in markets [LINDEMANN 2006A]. Companies seek to meet the needs of customers and create products that meet this demand at low cost.

Achieving these goals is seldom the responsibility of a single person or department in a company. Moreover, it is a shared task with various contributors. ULRICH & EPPINGER [2003] define product development as a set of activities beginning with the perception of a market opportunity and finalizing in the production, sale, and delivery of a product. Since this is a very complex task, operational and organizational structures of a company have to be managed. The organizational structure describes a company's configuration (e.g. hierarchy, departments, responsibilities) to achieve its objectives. The operational structure describes the framework managing the flow of processes.

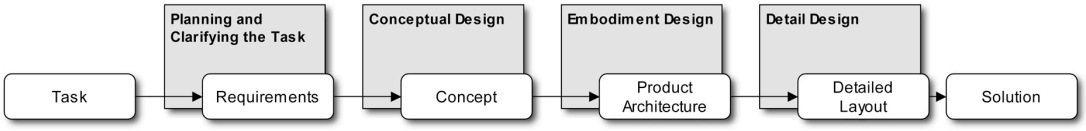


Figure 2-1: Overview of the Process of Product Development

Several authors present models for the workflow in product development [e.g. LINDEMANN 2006A, PAHL & BEITZ 2006, ULRICH & EPPINGER 2003]. These guiding frameworks describe the process of product development from defining the task to achieving a solution. A very generic, first overview of the process and its phases is presented in Figure 2-1. Starting with a task, the design gets more and more elaborated and refined until a final solution is achieved. Some "intermediate results" are a list of requirements, a concept, a product architecture, and a

detailed layout. They are elaborated starting from the planning phase, over the phase of conceptual design, the phase of embodiment design to the detail design phase. Each "intermediate result" is derived from the previous one and contains a higher level of concretization and information. The final solution then is the (physical) product ready to be manufactured.

In order to establish a common language, the terms introduced by PAHL & BEITZ [2006] were chosen for this thesis. Their model has become a widely accepted standard in the field of product development. Its description of the process of product development is tightly connected to the VDI Guidelines 2222 and 2221 [VDI 1977, VDI 1982, VDI 1986]. According to the authors, four main phases exist for the planning and design process [PAHL & BEITZ 2006, p. 65]:

- Planning and Clarifying the Task
- Conceptual Design
- Embodiment Design
- Detail Design

In the first phase (Planning and Clarifying the Task), product ideas are generated and the promising ones are selected. The result then is a product proposal. Mandatory requirements, existing constraints, and their importance are identified. The list of requirements summarizes what a product seeks to achieve. 'Requirement' is equal to the term 'customer needs'. Requirements (or respectively customer needs) are largely independent from the product to develop [ULRICH & EPPINGER 2003] and do not exclusively refer to the final customer. They also express any objective the product needs to fulfill (e.g. legal regulations, issues regarding its production, or budget limitations). Specifications are derived from the requirements and express the objectives in a measurable manner. Often more than one specification is needed to express one requirement. Both need to be updated continuously. Summarized, the information input for the development process is collected, structured, and specified in the phase of Planning and Clarifying the Task.

During the Conceptual Design phase, the development focuses on functions and working structures. Based on the requirements and specifications, suitable working principles are chosen and combined into a working structure. A further analysis is not possible until the principle is transformed in a more concrete layout. Therefore, a rough dimensional layout is produced and compared to the objectives and constraints identified in the first phase. It is possible that several principle solutions are elaborated.

In the phase of Embodiment Design, the product architecture is elaborated. ULRICH [1995] defines it as the arrangement of functional elements, the mapping from functional elements to physical components, and the specification of the interfaces among interacting physical components. In simple terms, the product architecture is the physical layout of the later product. Starting from a concept, the overall layout is determined. Sometimes, several preliminary layouts are produced in order to analyze them in a better manner and compare them to the specifications. By an appropriate combination, weak links can be eliminated and

the best layout can be obtained. All requirements, including the financial viability, have to be fulfilled by now.

The product architecture is then passed to the Detail Design phase, in which the final layout is laid down. Arrangement, forms, dimensions, and surface properties of all parts are determined. Furthermore, materials are specified, production possibilities assessed, and the final costs are estimated. The Detail Design phase then results in the specification of production and a final solution.

PAHL & BEITZ [2006] present a structured, systematic approach to develop products. Although the authors often recommend a flexible procedure in their book, it is seen as an example for traditional engineering and is often criticized for its inflexibility. The detailed descriptions and the step-by-step procedure rather emphasize a sequential than a flexible application.

Therefore, a more flexible model was chosen to be the underlying procedural model for this thesis. LINDEMANN [2006A, p. 45 ff.] presents an approach on a very high level of abstraction: The Munich Procedural Model (MPM). It is based on the fundamentals of problem solving approaches and is similar to the Engineering Method described by SEERING [2003]. The MPM is not only an overall framework but also suggests procedures for the individual phases of product development. It is suitable for all levels in product development and it was developed as a tool for the planning of development processes, as a means for orientation within processes in order to solve problems, and in order to analyze and reflect a procedure.

The MPM is not only suitable to describe the overall product development process, but can also be applied in each of the phases itself, on the top level as well as for individual steps within a phase. It can be applied in a recursive as well as in an iterative manner.

Independent from the form of application, the MPM highly emphasizes a flexible procedure. It provides guidance for less experienced users as well as enough flexibility for experts. The model suggests a standard path, but the connections between the single steps also allow iterations. In the following, the seven elements of the MPM are described in more detail (see Figure 2-2, italic captures):

- **Plan Goal:** At the beginning, the situation is analyzed regarding relevant parameters. These may be aspects of the market, customers, potential products, competitive products, etc. On an operative level, the goals are, for example, a successful team meeting.
- **Analyze Goal:** In this step, the objectives are defined and clearly described. Therefore, concrete requirements regarding the product are defined. It is important to document them in an adequate manner.
- **Structure Task:** This step aims to identify areas of high interest, prioritize them, and set a focus for the following procedure. In order to reduce complexity, it is reasonable to present the analyzed system on an abstract level or divide it into sub-systems. A further advantage of this step is the elimination of fixed ideas or conceptual barriers.

- **Generate Solution Ideas:** This step implicates the search for existing solutions and generation of new ones. Partial solutions are combined in various combinations in order to achieve an optimal overall solution.
- **Assess Properties:** Properties of the derived alternatives are analyzed regarding the fulfillment of the requirements defined earlier. With increasing concretization of the proposed solutions, the chances rise to identify a larger number of product properties.
- **Make decision:** In this step, the analyzed solutions are estimated and decisions are made regarding their implementation.
- **Ensure Goals Achieved:** This final step describes the preventive ensurance of the achievement of objectives. It aims to minimize potential risks early in the overall process. If necessary, actions are defined and implemented.

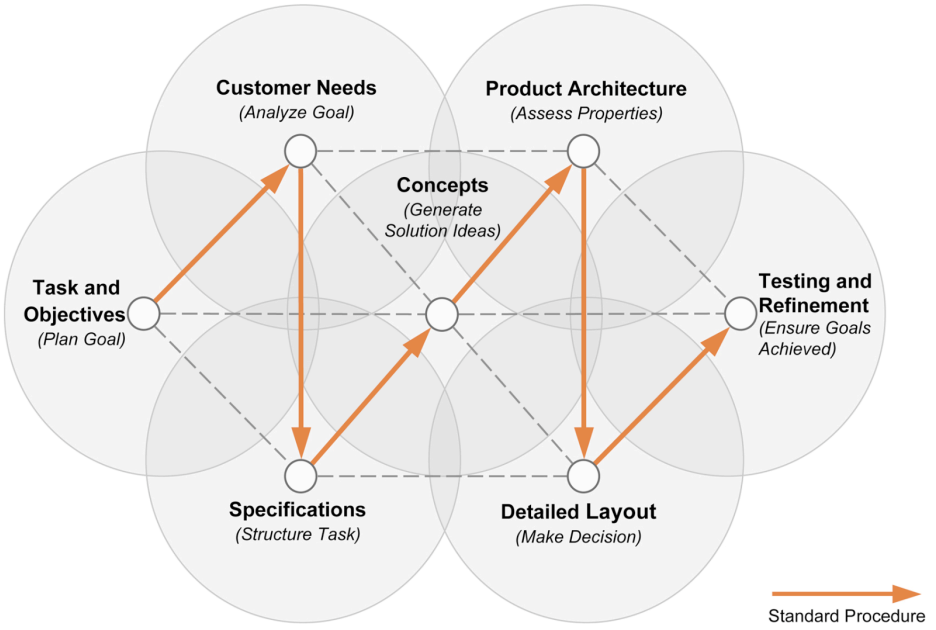


Figure 2-2: An Approach to Describe the Process of Product Development based on the Munich Procedural Model (MPM)

As mentioned previously, this thesis is based on the terms of PAHL & BEITZ [2006], but suggest the application of the more flexible procedure of the Munich Procedural Model. Both approaches are not contradictory to each other. On a high level of abstraction, the process of product development can be described by means of the MPM (see Figure 2-2).

The first phase of PAHL & BEITZ [2006], 'Planning and Clarifying the Task', can be interpreted as the first three elements of the Munich Procedural Model (see also Figure 2-3). First, the task and objectives have to be clarified. Afterwards, requirements regarding the product, the customer needs, are identified. And in the last step, the requirements are transformed into specifications: exact and neutral descriptions of all aspects of the product to develop.

In the phase of Conceptual Design, alternative solutions are generated. This phase corresponds to the step of generating solution ideas. Once, suitable alternative solutions are chosen, they are passed to the phase of Embodiment Design. In Embodiment Design, the concept is defined in more detail and elaborated into a physical layout, the product architecture. Properties of the future product are determined and can be analyzed regarding the fulfillment of the requirements. The phase of Detail Design then represents the refinement of the product architecture into the final layout and the preparation for production.

The last step of the MPM, "Ensure goals achieved", indicates the need of a 'Testing and Refinement' phase. This step is not explicitly expressed as a phase in the framework of PAHL & BEITZ [2006]. Nevertheless, the authors emphasize testing throughout the recommended procedure. ULRICH & EPPINGER [2003, p. 9 ff.] also introduce this step in their description of a product development process. Therefore, this phase is added to represent the last element of the MPM.

For the highest level, the elements of the MPM and the corresponding phases of product development are shown in Figure 2-3.

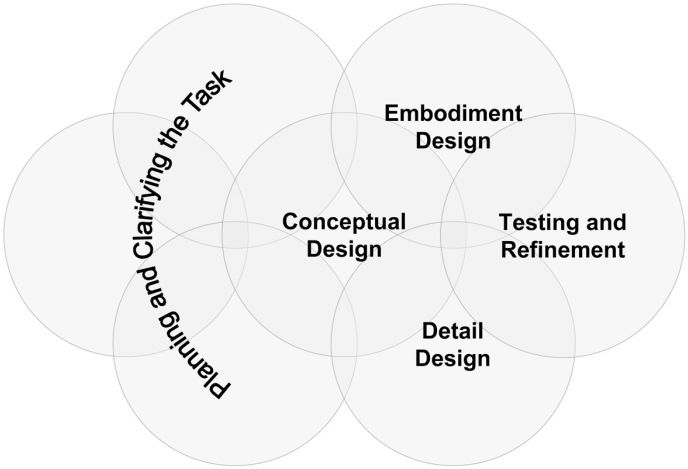


Figure 2-3: The Phases of Product Development in the Munich Procedural Model

In order to prevent misunderstandings, it has to be noted that there are some differences in European and American literature regarding product development and design. The term "concept" is interpreted much broader in American literature [e.g. ULRICH & EPPINGER 2003]. It can refer to drafts, working principles, or product architectures – basically anything before the final solution is chosen and produced. PAHL & BEITZ [2006], however, represent a European point of view: Their definition is stricter and regards a concept as the specification of the working principle. When the concept is more elaborated and becomes defined in more detail, it is called layout or product architecture. They emphasize a three-step-approach (concept, rough design, detail design) whereas in American literature only two notions (concept, detail design) are common.

The combined model of the MPM and the phases described by PAHL & BEITZ [2006] describes the interpretation of the product development process in this thesis (see Figure 2-2). The MPM forms the guiding process model whereas Pahl & Beitz' terms describe the

individual phases on the top level of the PD process. The approach of PAHL & BEITZ [2006] was chosen because their three-step-approach represents a more accurate description of the development process. The three-step-approach prevents misunderstandings, especially regarding the term 'concept'. Since this thesis investigates an approach to mitigate deficiencies in product architectures, it is important that the terms are distinguished from each other.

Additionally, it is hoped that the flexible approach of the MPM mitigates the disadvantage of Pahl & Beitz' model, which is often criticized for its inflexibility. This combined model forms a guiding framework in this thesis and builds a common language. This thesis will also take the perspective of Lean Product Development into account, which is described in the following section.

2.2 Lean Product Development

With their often cited book "The machine that changed the world" WOMACK ET AL. [1991] described a revolutionary, new form of production management developed at the Toyota Motor Company and introduced the term "lean manufacturing". Also known as the Toyota Production System, lean manufacturing has become a synonym for improving productivity and effectiveness in the field of production and manufacturing.

By carefully adopting, tailoring, and continuously improving the techniques of the Western manufacturing industry, Taichii Ohno and Shigeo Shingo of the Toyota Motor Company developed new ways and practices for Toyota's production plants in Japan. Compared to mass production, they achieved the same results with (among others) half the human effort, half the manufacturing space, half the investment tools, half the engineering hours, and half the time to develop new products [WOMACK ET AL. 1991]. The knowledge they gained has changed the then existing view of effective and efficient production.

Over years, Ohno and Shingo developed not only a set of instruments and tools but created a philosophy: Lean Thinking. Due to the enormous success of Toyota's production system, enterprises started to apply lean principles – not only in the field of production and manufacturing but in all functional areas of a company [MORGAN & LIKER 2006, WOMACK ET AL. 1991]. Soon, the philosophy of Lean Thinking was used to improve the performance of processes in various different areas.

The philosophy is based on five principles: Value, Value Stream, Flow, Pull, and Perfection [WOMACK ET AL. 2003]. In the following, they are described in more detail.

Value – the most basic principle – represents the value from the customer's point of view. The opposite of value is defined as 'muda' – the Japanese term for waste. One of the fundamentals of Lean Product Development is the paradigm of "creating customer value". One possibility to create customer value is the elimination of waste. By eliminating waste, costs can be reduced and thus, the product costs are decreasing. The product becomes more affordable, which is valued by the customer. Therefore, a product development organization should align all objects, focus energy on the customer, and eliminate waste from the system [MORGAN & LIKER 2006, p. 19]. All processes either add value to the product or not (value

adding VA, non-value adding NVA). Some of the non-value adding processes may still be necessary and represent required, but non value-adding activities (RNVA). One of the objectives of Lean Thinking is to eliminate, or at least minimize, all non-value adding activities.

Value Stream describes the generation of value throughout the company. All activities of a company are integrated – from the beginning to the end of a process the whole system should be involved.

Flow means the flow of value stream throughout a company. After the elimination of all boundaries, the flow of information, products, or anything that creates value has to be optimized. Thus, substantial savings regarding times and cost can be achieved.

Pull describes a basic control principle. By contrast to the push principle, an activity will only start after being requested by a downstream activity. As this is applied throughout the whole value chain, the production is controlled by the end-customer.

Perfection is a synonym for an ideal order and condition of a system. This can only be achieved through continuous improvement and the involvement of all parties – as a system will never be perfect.

Those five elements form the guiding principles in Lean Product Development. The designer has to keep them in mind for all task related to the development of the product. According to MORGAN & LIKER [2006, p. 52], Lean Product Developments means to make sure that designs are compatible and feasible before they are completed. The authors also point out that great risks occur by completing individual designs too quickly. A result is often a large amount of late term changes.

When individual designs are matched up with related components or were already assessed for manufacturability, changes are more limited and far more expensive than in earlier phases. These late term changes can be interpreted as wasted development time and resources. If they are avoided, costs can be saved and, thus, the affordability of the product increases. Note that the term ‘waste’ does not refer only to the product to develop but also to the product development process itself.

BROWNING ET AL. [2002] argue that the reduction of risk eliminates unnecessary costs and therefore creates value. Thus, it can be concluded that Lean Product Development highly emphasizes to identify and assess possible shortcomings of a product as early in the process as possible.

2.3 Risks in Product Development

This section gives a first introduction to risks in product development. First, risk is defined and distinguished from the term 'failure' (section 2.3.1). A general overview of risks in the phase of value creation is given in section 2.3.2. In the following section (2.3.3), risk is more specified for the phase of embodiment design.

2.3.1 Terminology of Risk and Failure

The interpretation of risk has many nuances and tends to be more negative. However, its basic meaning is indeed neutral: it is an occurrence with a specific probability to happen and specific consequences. The absolute interpretations are opportunity on the positive side and threat on the negative side.

MERRIAM-WEBSTER [2001] defines risk as "the product of the amount that may be lost and the probability of losing it". This very generic definition applies to a number of various fields. In this thesis, risk is interpreted as an occurrence with an unknown probability and consequences adversely affecting the intended performance of the product to develop. Thus, the consequences can also be expressed as an undesired derivation from the planned objectives.

In product development, the term risk is sometimes associated with problems and uncertainties in terms of technical reliability [BAUCH 2004, p. 24]. Additionally, product development has to deal with certain technical risks associated with a concept, product, manufacturing or assembly process, or services regarding the product – to name only a few. Technical reliability however, is only one aspect among them.

Technical reliability, also expressed by means of the term 'failure', can be interpreted as a technical risk, but only in the loosest sense of the word [PDMA 2002, p. 206]. Whereas a risk is an occurrence with a specific probability of occurrence and it is not known if it will happen or not, a failure is an issue that will happen. The crucial question is "how often will this failure happen?" (e.g. a certain amount of parts out of 100). Risks with a probability of occurrence of 100% are no longer uncertain. They have become problems that have to be tackled. Therefore, a failure has to be regarded as a problem.

It can be summarized, that failure is a problem that will happen and eventually needs to be prevented. If there is no need to prevent it, the failure may not be severe or an effective reaction plan already exists. In contrast, the occurrence of a risk is uncertain. A good, informal description for a risk is the phrase "Maybe it will happen, maybe it won't."

It has to be noted, that risks should not be exclusively regarded as threats. Some approaches in risk management suggest taking opportunities into account [e.g. HILLSON 2002, PDMA 2002]. Opportunity is the positive interpretation of risk and can also be expressed by means of the term 'chance'. This optimistic view has not been appealing in related literature. Nevertheless, success in business and product development has always been associated with taking the right and measured risks. According to PWC [2007], there is no innovation without

risk. And without innovation, there is no economic growth [PWC 2007]. If a company is willing to take a large risk, it is presumable that there is a huge opportunity or chance as well. However, even if the positive interpretation of risk was widely accepted, it would not be regarded in a neutral manner in risk management literature.

Therefore, one should think of a new way to perceive a risk. It is strongly recommended in this thesis to regard risk in the meaning of a challenge. Challenge describes the basic meaning much more objective: it includes the presence of threats, but also chances. Furthermore, it indicates the existence of own responsibilities, efforts, and options – summarized as the ability to control and manage a situation. On the contrary, risk has become a term that is understood as something far more abstract and less tangible. However, unseen risks cannot be perceived as challenges and are, according to CHRISTOPHER [2003], far more dangerous. Thus, the earlier risks can be identified, the better the chances are to master those challenges.

2.3.2 General Overview of Risks in Product Development

In product development literature, several kinds of risks and categories are enumerated. This section will give a brief, general overview of risks in product development and different types of risks.

As product development is a combined task to create information and as it is influenced by numerous factors [BAUCH 2005, LINDEMANN 2006A], it is presumable that a various number of uncertainties exists. While concentrating on performance, time to market, and cost, uncertainty adds a further dimension, which designers have to manage [ESD 2004, p. 20].

Especially the "fuzzy front-end", as early phases in product development are sometimes called, includes "unknowns" about user requirements, user diversity, and potential competition [SKELTON & THAMHAIN 2005]. As design work proceeds, certainty increases that the evolving product design will achieve the objectives and be the final product [BROWNING ET AL. 2002]. And with increasing availability of information, the overall risk in product development decreases (see Figure 2-4). LINDEMANN [2006B] adds the aspect of cost and argues that the ability to influence costs decreases as the product development process proceeds. Thus, it is important to identify and mitigate potential deficiencies as early as possible.

The first phase of product development, Planning and Clarifying the Task (see Figure 2-3), is not shown in this figure but it can be assumed that the amount of risks is still considerable due the high level of uncertainty. Whereas in the phase of Conceptual Design several aspects have not been defined or are not known, more and more characteristics of the later product will be determined now. Therefore, the overall number of risks is decreasing and continues decreasing over the following periods. With increasing knowledge, former risks can be eliminated or tackled. The graph can be interpreted that at the end of the Testing & Refinement Phase the number of remaining risks is very low because they have either occurred (and become problems) or not. However, a small number of risks still remains, for example those related to production or the unknown risks from earlier phases that have never been identified.

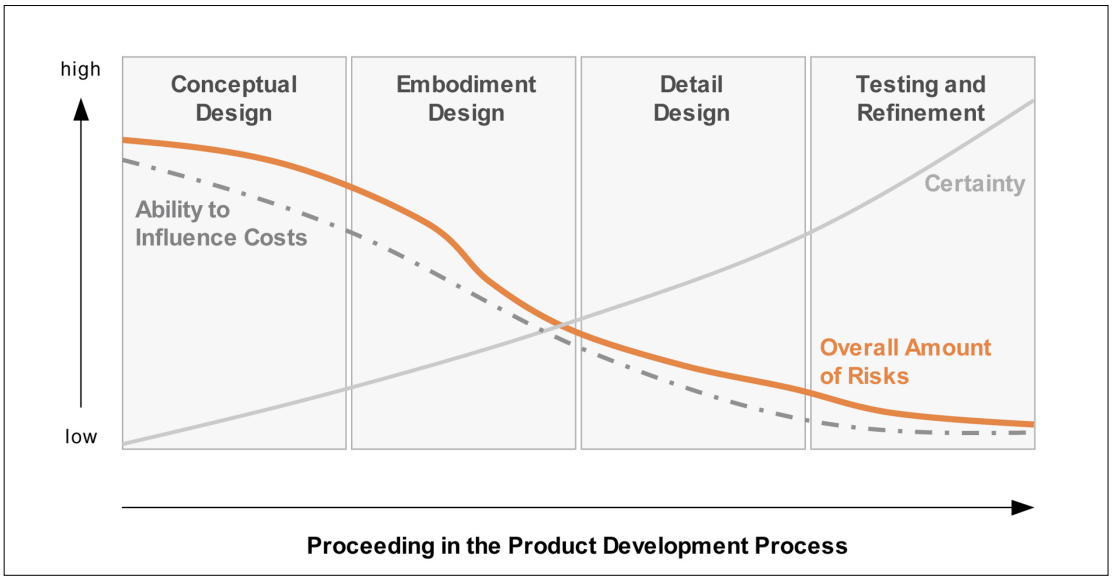


Figure 2-4: Decrease of Risk as Product Development Proceeds [adapted from BROWNING ET AL. 2002, LINDEMANN 2006B]

Several authors in product development have tried to classify risks and the variety of classifications is as manifold as the character of risk itself. Approaches are discussed, among others, by [BROWNING 1998, CHASE 2001, KAIZER ET AL. 2005, NEGELE ET AL. 2005, PDMA 2002, and THAMHAIN 2004] (see Figure 2-5). Each of the authors presents a classification from a slightly different point of view. Some authors define the types more precisely than others [e.g. KAIZER ET AL. 2005]. Other authors describe more generic types of risks. For example, OEHMEN [2005] identified four categorizations types for risks classifications: Cause-, impact-, time-, and meta-oriented categorization. He also gives some examples: E.g. within the impact-oriented categorization, risks are classified by either their type of impact or magnitude of impact.

This thesis will not present a further classification for risks. Only an overview over existing types and a first idea about the diversity of risks should be imparted. Thus, this list is not exhaustive. For further investigations, it is recommended to study the work of the authors named above.

In general, it is reasonable to assume that defining risk categories and types depends on the perspective. One possible perspective may be a hierarchy level of the focal system (e.g. teams, department, division, company). Another perspective might be derived from the individual tasks that have to be performed. However, all perspectives have in common, that the distinction of internal and external risks depends on how a system is defined.

In Figure 2-5, an overview of some risk types is given. The types are located according to the responsibilities of marketing, design, and manufacturing. Process and project management is added as an overall task. External risks take potential occurrences outside the sphere of influence into account. From this perspective, internal risk types consider (among others) performance risks, financial risks, or quality risks of the product. Regarding the process of

development, organizational risks, schedule risks, budget risks, or programmatic risks etc. exist. External risks regard the supply chain and sourcing, competitors, or the environment in general.

The figure does not only give a good overview about the variety of risks, but also indicates their complexity and potential interaction. For example, the sales division may deal with the risks that they cannot satisfy the customers' demand. The production unit of a company, however, concentrates on manufacturing risks. Both are tightly connected and the later risks considerably influence the supply availability of the company. Another example for the interaction of risks are manufacturing risks and schedule risks, which are also tightly connected. If major difficulties occur while manufacturing a product, it is almost certain that there will be schedule delays as well. Commercial viability risks may be a good example for the aspect of interaction between business units. E.g. they may result from coordination deficiencies between the marketing and design divisions.

This thesis investigates risks in the embodiment design phase, which belong to the category 'Design' in Figure 2-5. Good examples for a risk in this phase are the non-achievement of desired functions of the later product or the oversight of potential weaknesses. These risks would influence others as well, e.g. public acceptance risks (marketing risks), manufacturing risks, programmatic risks (management risks), or supply risks (external risks). Risks that may occur in the embodiment design phase in particular will be discussed in the following section.

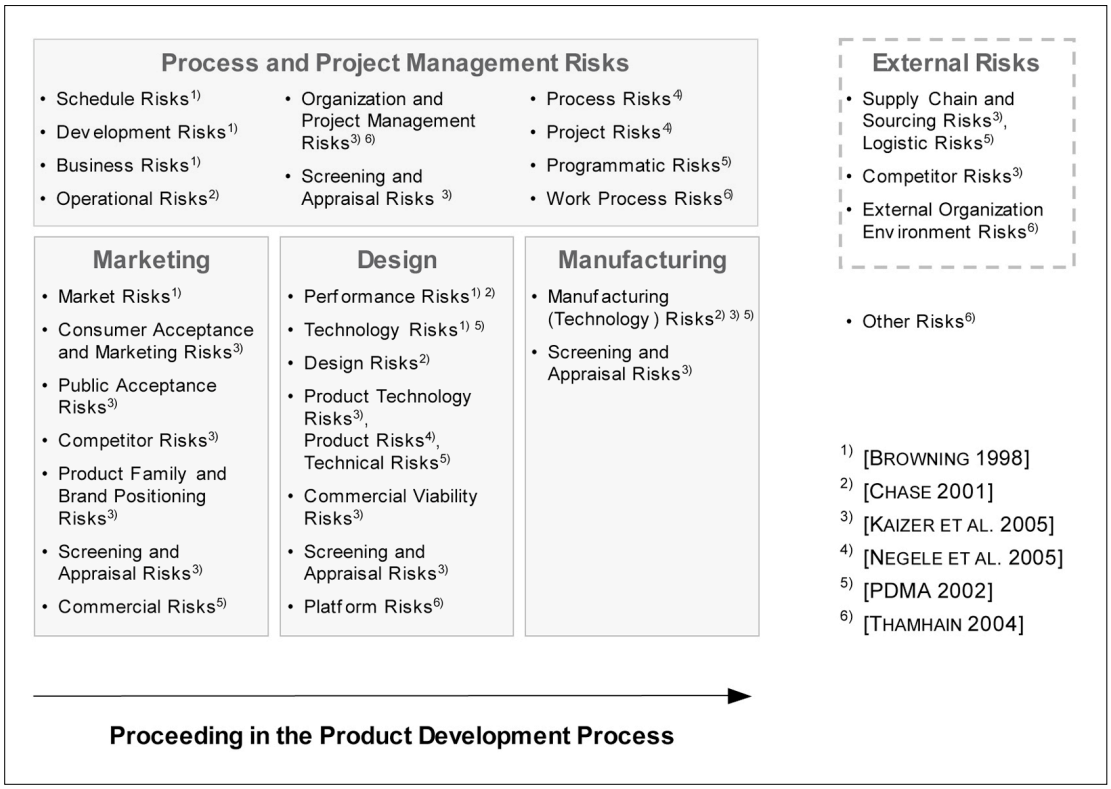


Figure 2-5: Risks Categories in Product Development Literature

In general, many reasons can be assumed where and why risks emerge: Interfaces could be a place where a lot of risks evolve. Additionally, different interests, difficult strategies, communications problems within business units themselves and in between, etc., influence the increase of risks. Another example would be the scenario that a missing overview enhances the misjudgment of a situation and, thus, inhibits an early identification of risks.

It would go far beyond the scope of this thesis to describe every type in detail. Nevertheless, the figure indicates the manifoldness to define types of risks and the authors mentioned are a good start for a deeper analysis. This thesis focuses on risks regarding the performance of a product, especially those emerging in the phase of embodiment design. Its specific risks will be discussed in the next section.

2.3.3 Risks in the Phase of Embodiment Design

At the early design stage of the product development process, little information is available to the designer. However, decisions have to be made during the Conceptual and Embodiment Design phases determining later characteristics of the product such as weight, costs, etc. In the phase of Embodiment Design, the product architecture is elaborated and the overall layout determined. All requirements regarding the product have to be fulfilled before the layout is passed on to the Detail Design phase.

Requirements represent the characteristics the emerging product is expected to fulfill [LINDEMANN 2006A, p. 327]. They describe objectives of a product qualitatively whereas specifications quantify those and break them into measurable parts. Typically, specifications are derived from the requirements and consist of two parts: a verbal description and a related unit. If possible, a target value with a tolerance is assigned. The formulation should be solution-neutral, positive, and precise [ULRICH & EPPINGER 2003, p. 16; LINDEMANN 2006A, p. 107]. The lists of requirements and specifications are dynamic documents – during the process of product development both are changed, new requirements (respectively specifications) are included, and superseded ones are eliminated.

Product development is driven by requirements, and especially the phase of Embodiment Design is highly dependent on them. But a perfect specification of the requirements does not guarantee a perfect product. Requirements are not always fulfilled through a solution [ALMEFELT ET AL. 2006]. The authors describe three possible reasons that may lead to an unfulfilled requirement: First, not all requirements are followed-up in the same manner. Requirements without “owners” or stakeholders often “fall between the stools” and aren’t fulfilled appropriately. Focused requirements are followed up through daily work or regular meetings, while other requirements are barely followed up at all. Second, the requirement specification is interpreted in different manners and cannot be fulfilled in the originally intended manner. Third, the knowledge about the requirement is insufficient. Late introductions and changes, communication problems, as well as unclear rules further enhance the risk that a requirement is not fulfilled.

But the final state of the product is determined by how successfully the requirements have been incorporated into design solutions. This is a result of activities such as follow up,

prioritization and balancing of requirements. The field study showed that these issues are more problematic to manage and less carefully organized than the requirement specification itself [ALMEFELT ET AL. 2006, p. 124].

Furthermore, it is important to keep in mind that meeting the requirements is not a question of yes or no. To what extend they are met influences, along with the operational requirements, the performance of the process, and subsequently the quality of the generated information [GRAEBSCH 2005, p. 46]. The author analyzed product development from a perspective of information and communication. But his conclusion can be extended to requirements in general. Meeting the requirements must not be regarded as a binary question: in fact it is crucial to what extent the requirements are fulfilled.

2.4 Summary

Chapter 2 presented the underlying frameworks and definitions in product development. In section 2.1, the phases of product development are described. Therefore, the approach of PAHL & BEITZ [2006] was chosen and connected to the flexible framework of the Munich Procedural Model (MPM). Together, both form the interpretation of the product development process on the highest level.

Afterwards, the perspective of Lean Product Development is taken into account (section 2.2). The philosophy is described and its five paradigms – value, value stream, flow, pull, and perfection – are presented. Lean Product Development emphasizes the creation of customer value and the reduction of waste. Since the reduction of risks eliminates unnecessary costs and time, it can be argued that the reduction of risk creates customer value.

Section 2.3 intends to present an introduction to risks in product development. First, the terms risk and failure are defined and differentiated from each other in section 2.3.1. Afterwards, a general overview of risks in product development is given (section 2.3.2). A literature review about risk types and classifications is presented. It is shown that many potential classifications of risks exist, which interact and influence each other.

Since this thesis concentrates on the phase of Embodiment Design, risks in this phase of value creation are presented in section 2.3.3. It is crucial for a product's success that the requirements are fully incorporated into the design. However, a survey in the Swedish automotive industry showed that this is often not achieved. Further potential risks, e.g. supply risks or legal risks, were also briefly described.

This chapter intends to present the underlying frameworks and definitions in order to establish a common language. The process of product development and the philosophy of Lean Product Development are described. Additionally, a first introduction to risks is given. The following chapter will discuss the state of the art in Risk Management and Embodiment Design.

3 Analysis of the State of the Art

As presented in section 1.3, this thesis will focus on Risk Management, the Failure Mode and Effects Analysis (FMEA), and the phase of Embodiment Design in product development. This chapter will characterize and discuss these three elements.

At the beginning, the fundamentals of Risk Management are presented in section 3.1. Afterwards, in section 3.2, the FMEA is described and its similarities to Risk Management are investigated. Then, the fundamentals of Embodiment Design are discussed in section 3.3. An interim summary about the potential of the FMEA as a risk management tool completes the analysis of the state of the art (section 3.4).

3.1 Risk Management

The first section gives a general introduction to Risk Management (section 3.1.1). Existing methods and frameworks from different fields of engineering are reviewed and characterized in section 3.1.2. Afterwards, similarities and differences of the frameworks are discussed (section 3.1.3). Requirements and recommendations for the method to develop are derived simultaneously.

3.1.1 General Introduction to Risk Management

In recent years, risk management has become popular in various fields of engineering. Originally located in the financial sector, basic theories and insights have been transferred to the fields of product development, project management, logistics or supply chain management. In the following, the underlying fundamental characteristics of risk management are introduced for all of them. The differences will be discussed at a later point.

In general, managers seek to achieve the desired objectives. Some of the characteristics of their jobs are: various collaborators and contributors, challenging objectives, resources needed, a timeframe, and a number of stakeholders. The duties often bear a large complexity and dynamic structures. Therefore, managers have to deal with uncertainty and unforeseen events. It is this realization, which has led to the undoubted popularity and profile of risk management. It offers a structured approach to manage the inevitable uncertainty of those duties [HILLSON 2002].

MCGRAW-HILL [2002] defines risk management in general as the overall systematic approach to analyze risks and implement risk controls. In the field of product development, the Munich Procedural Model sees it as part of the step “ensure goals achieved”: The minimization of risks and a preventive ensurance should take place in an early phase of design in order to achieve the desired objectives [LINDEMANN 2006A, p. 49]. Risk management is tightly linked to the success of a product development process and the achievement of overall goals.

SKELTON & THAMHAIN [2005] further point out that "a common denominator to product success appears to be the ability to deal effectively with […] risks". Another reason for this might be the fact, that teams, which can anticipate risks and respond effectively to them, are the ones that develop agility and are more likely to succeed [PDMA 2002, p. 187].

From a perspective of Lean Product Development, risk management is not only connected to the success of a product development project. Moreover, it is associated with the creation of customer value. BROWNING ET AL. [2002] even underline the equation of reducing risks and creating customer value. They argue that reducing uncertainty in product development reduces costs (e.g. for resource buffers and options) that are passed along to the customer. Reducing risks improves the affordability of a product and as a consequence its customer value.

In order to describe the process of risk management, various frameworks in several fields of engineering have been developed. They will be presented in the next chapter and discussed afterwards in section 3.1.3.

3.1.2 Existing Risk Management Frameworks

Nine frameworks from different domains have been reviewed (see Figure 3-1). In product development, three approaches are described: a generic approach from the perspective of Lean Product Development [OEHMEN 2005], a step-by-step procedure by the Product Development & Management Association [PDMA 2002], and an approach from the perspective of Systems Engineering [NEGELE ET AL. 2005].

Two approaches from the perspective of Project Management have been reviewed [PMI 2004, SMITH 2003]. In Supply Chain Management, four approaches are described. ZIEGENBEIN & SCHNETZLER [2005] present a nine-step approach. CHRISTOPHER [2003] developed a self-assessment workbook for companies. The supply network risk tool of HARLAND ET AL. [2003] starts with a defined problem or concern. And NORMANN & JANSSON [2004] describe Ericsson's risk management process.

All of them follow a similar schema, which is characterized in the following. A very brief summary for the individual frameworks is given from page 6 to page 25. The summary is useful for a deeper understanding. For the general understanding, it is not deemed necessary and can be skipped. If one is interested in more detail of a particular framework, it is recommended to study the respective literature itself.

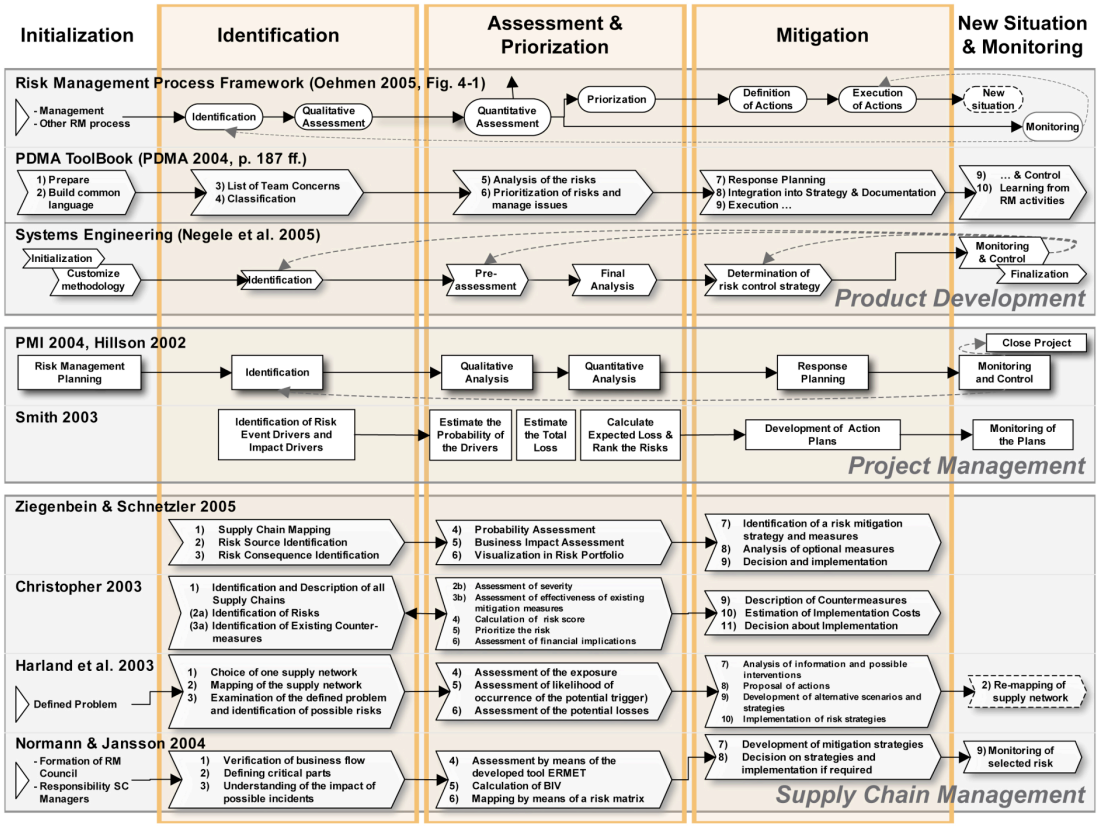


Figure 3-1: Overview over Existing Risk Management Frameworks

All approaches divide the process roughly into five phases, as also shown in :

- **Initialization**: The process of risk management is started, either by a decision of the management or another risk management process. The preparation needed is also assigned to this phase.
- **Identification**: In this phase, risks are identified and described in more detail.
- **Assessment and Priorization**: After the identification phase, the risks are assessed - mostly regarding the two dimensions likelihood of occurrence and impact of a risk. This may happen in a quantitative, qualitative or semi-quantitative way. Usually, numerical values are assigned and the risks can then be prioritized by means of them.
- **Mitigation**: Strategies and measures are developed to mitigate the risks. This will be accomplished first for the most severe ones. As well as for other risks, if this can be achieved very easily and is cost-effective. Decisions have to be made about which measures should be implemented and which not.
- **New Situation and Monitoring**: After the implementation of the mitigation measures, a new situation is achieved. The effectiveness of the measures will be controlled and the risks will be monitored.

OEHMEN [2005] unified existing risk management approaches in product development into an overall process framework. Amongst others, he especially reviewed the work of HALL [1998], PMI [2004], SMITH & MERRIT [2002], and STAMATELATOS [2001]. He identified suitable methods for each phase of the framework, altogether 66 methods. His general framework consists of an inner, an outer and an integration circle (see Figure 3-2). Receiving a trigger impulse either from the management, monitoring activities or another risk management process on a higher level starts the inner circle. First, potential risks are identified. They are described in detail in the so-called phase of "Qualitative Risk Assessment". Within the Quantitative Risk Assessment, the probability of occurrence, the severity of impact, and the time frame of a risk are expressed through numerical values. According to their description, the risks are prioritized. Then, mitigation measures can be defined to minimize losses. As a last step of the inner circle, the actions will be executed. Risks as well as the performance of the risk management process will be monitored in the outer circle. If indicated, the monitoring activities will re-initiate the inner circle. The third circle, the integration circle, links the risk management process to other risk management activities or to an overall enterprise approach.

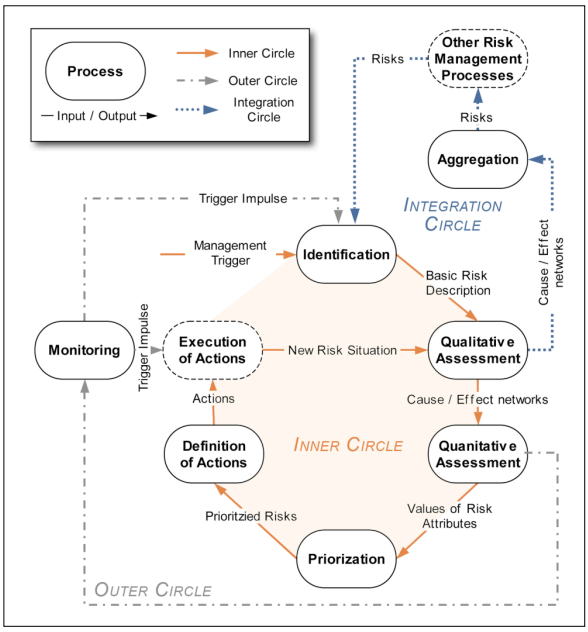


Figure 3-2: Risk Management Process Framework of OEHMEN [2005, Fig. 4-1]

The PDMA ToolBook [PDMA 2002, p. 187 ff.] describes a ten-step risk management approach. The objective is to "anticipate threats, make decisions to prioritize the threats, and apply appropriate countermeasures to effectively avoid or mitigate the risk event." For the preparation, a checklist of six tasks is given. In the second step, a common language is built and the team's mental models are aligned. A clear distinction is made between a risk and an issue. To generate a list of the team's concerns, several identification techniques are recommended. Then, after the risks and issues have been identified, they are classified into groups. For the analysis, a key figure named "risk exposure" is introduced, which is calculated by multiplying the probability times the consequences of the risk event. Several risk quantification techniques are discussed. Afterwards, the risks and issues are prioritized.

Risk responses as well as actions to manage the issues can be planed. The author describes four different risk response strategies: Risk avoidance, risk mitigation, risk transference and acceptance. Finally, the risk responses are integrated into the program strategy and document project baseline commitments. The measures are then executed and controlled. Furthermore, "Learning from Risk Management" is explicitly addressed as the last step.

NEGELE ET AL. [2005] present a practical risk management approach from the perspective of Systems Engineering. The approach is tightly connected to the project management of product development. First, the project management initializes the risk management process. Responsibilities are determined, a budget is planned, and appropriate methods are selected. Afterwards the methodology is customized in order to adjust it to the specific objects or system. Within this phase, a risk questionnaire is generated to identify risks in a systematic way regarding the three categories: product risks, process risks, and project risks. By means of the questionnaire, risks can be identified and assessed regarding their likelihood of occurrence and their impact. The set of risks is analyzed and risks are prioritized to achieve a manageable set or risks, so called "hot spots". Responsibilities for the hot spots, as well as for the remaining risks are assigned. By monitoring and controlling activities, the risk manager measures the effectiveness of the defined measures. NEGELE ET AL. [2005] also propose to iterate the main process steps. The objective is to look into specific details, to identify new risks and to check the overall risk level. In the final phase, indicated by the start of production (SOP), the risk management process for product development ends. The risk management process is reviewed regarding its effectiveness and efficiency. It is suggested to apply a similar approach for production and services.

HILLSON [2002] explicitly addresses the ambiguous meaning of risk. He expands traditional risk management to deal not only with the management of threats but also with opportunities, defined as risks with positive effects. His framework is based on the procedure of the Project Management Institute [PMI 2002 or see its update PMI 2004]. Six phases form this approach: Planning, Identification, Qualitative Analysis, Quantitative Analysis, Response Planning, Monitoring and Control. The first phase addresses the initialization of risk management. In the Identification phase, risks that might affect the project are determined and described. They are analyzed regarding their probability of occurrence and their impact, and afterwards prioritized (Qualitative Analysis). The impact on overall project management goals is numerically estimated in the Quantitative Analysis. Options to enhance opportunities and minimize treats are developed in the phase of Response Planning. The response plans are executed, risks are monitored and new risks identified in the last phase (Mitigation and Control).

Another risk management approach on a project level is described by SMITH [2003]. The author suggests to distinguish between the probability of a risk event, the probability that the impact is realized, and the total loss of workdays in the worst case. The expected loss can then be calculated by multiplying the key figures. The risks can then be prioritized by means of the expected loss and action plans can be developed. Two types of actions are suggested: prevention plans and contingency plans. It is also enhanced that responsible individuals should be designated, as well as a due date. Means to measure the progress and sufficient resources have to be provided. Observing the expected loss value then monitors the progress.

In their over-all framework for Supply Chain Risk Management, ZIEGENBEIN & SCHNETZLER [2005] present an approach consisting of three phases: identification, assessment, and mitigation. Each phases consists of three process steps. The first step is the visualization of the analyzed supply chains by means of the Supply Chain Operations Reference (SCOR) model. A generic risk catalogue or techniques like brainstorming help to identify risk sources to the goods flow. In the third step, possible consequences for each risk source are estimated. Afterwards, the probability of occurrence is evaluated by means of the Fault Tree Analysis. The financial impact of each risk is calculated by means of the Business Interruption Value (BIV). The BIV is determined by the loss gross margin, costs of idle capacity, and additional inventory. In the last step of the assessment, all supply chain risks are visualized in a risk portfolio. The probability of occurrence and the BIV form the dimensions of the portfolio. The portfolio is divided into quadrants, and mitigation strategies for each quadrant are presented. Different mitigation options are discussed, compared and assessed. Mitigation measures that meet the criterion of cost-effectiveness should be implemented. For the other ones, individual decisions have to be made based on the attitude towards the risk.

CHRISTOPHER [2003] presents a self-assessment workbook for risk management in supply chains. He argues that visible risk may be – not necessarily can be – managed, and that unseen risks are far more dangerous. In the workbook, the company's supply chains are identified and described. This may be an extensive task depending on the size of the company. Afterwards, each chain is analyzed regarding risks in five categories (demand, supply, process, control, environmental risks). In the next step, the severity is estimated by a 0,1,2 scale. Furthermore, existing mitigation measures in the current operation practices are taken into account. Their effectiveness is also rated by means of a 0,1,2 scale. The multiplication of the key figures then forms the overall risk score. For each risk, its implications are evaluated: The financial impact has to be estimated, the duration of the risk event (also expressed in a monetary amount), as well as the cost for recovery. Thus, a simple estimation of the total costs can be achieved. Corrective actions are also identified, and their implementation costs as well as running costs estimated. This allows the management to weight the possible financial consequences of a risk against the investments to mitigate them.

The supply network risk tool by HARLAND ET AL. [2003] is a tool that addresses the three core processes of risk management: identification, assessment, and mitigation. By means of a defined problem or concern, a supply network is chosen. The network is described and possible risks are identified. The likelihood of an occurrence is defined accurately: first, the extent on the exposure to risk is estimated, and second, the likelihood that a potential trigger will realize the risk is assessed. After the assessment of potential losses, the gained information is analyzed. Possible interventions are considered and actions proposed. Alternative scenarios and strategies are developed and, if reasonable, implemented. A variant of monitoring is proposed by starting over with the first step again.

NORRMAN & JANSSON [2004] describe the risk management approach of Ericsson. After a serious interruption in one of their key component's supplies, the company established a proactive risk management. It is tightly aligned with the company's structure: A risk management council with representatives from all kinds of business areas was formed. It reports via the Corporate Risk Manager directly to the CEO. Furthermore, all supply chain

managers are fully responsible for applying tools and processes to manage risks in their supply chains. In the identification phase, Ericsson verifies the business flow by mapping the supply chain upstream. Critical components are identified and classified by means of their number of sources. Then, Ericsson tries to understand the potential impact of a risk by calculating the "business recovery time". By means of a customized tool, the suppliers of critical parts are then assessed regarding various aspects. The risks are quantified by looking at impact and probability. The impact is calculated by means of the Business Interruption Value (BIV): the gross margin multiplied with the business recovery time. The assessments form the basis for a risk matrix to visualize and compare the results. Once the risks are identified and assessed, mitigation strategies are developed and decisions on them can be made. Ericsson calls this phase "Risk Treatment". If required, actions are implemented. By means of templates and spider-web-diagrams, Ericsson monitors the responsible "owner" and the development of certain risks. The company also emphasizes the reporting of incidents and development of provident contingency plans.

3.1.3 Discussion

It has been shown in the previous section that authors from several fields describe the process of risk management. No matter whether the frameworks were meant for product development, project management or supply chain management, all approaches are very similar. This may originate from two reasons. First, the nature of a risk remains the same. It is an event with an unpredictable probability of occurrence and an uncertain impact on the outcomes.

Second, all domains deal with a complex process in a large network of suppliers and customers. The overall process is composed of process fragments: transformation steps undertaken by process elements and dependent on customer-supplier relationships (see Figure 3-3). The focal element is dependent on a supplier that delivers the necessary input. The focal element then conducts the process steps necessary to achieve its objectives and deliver the output demanded by a customer. The process steps seek to transform the input into the desired output. Of course, this figure highly abstracts the complexity. It only shows the fragment that forms the basis for the processes in product development, project management, and supply chain management.

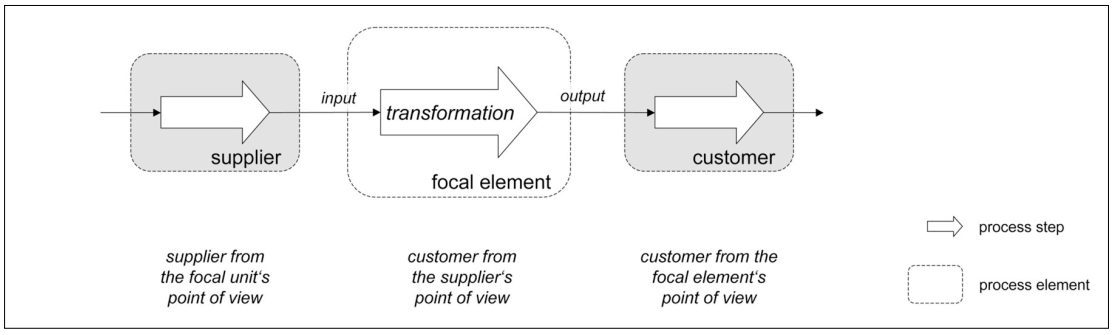


Figure 3-3: Basic Process Fragment

In product development, suppliers and customers are often, but not necessarily, inside the company. "Customer" does not only refer to the end consumer of the product, moreover also to any party that is interested in the immediate deliverables. These customers are also called stakeholders. The processed good in a product development process is information (cf. [BAUCH 2004]). In project management, it can be information as well as materials, whereas in supply chain management the main good is a physical product – although there is also a flow of information, of course.

It is reasonable that the similarities in the nature of the processes may be a reason for the similarities in the risk management approaches. However, this is not empirically proven. For all domains, it can be generalized that risks either emerge during the transformation phase, on the interfaces, or outside the sphere of influence.

Although all frameworks describe a generic framework for risk management, practical and easy applicable approaches for the challenges in product development are missing. The frameworks presented deal with risks regarding the product development process, but not the emerging product itself. Only a generic procedure is described, but it lacks concrete steps to achieve the objectives. The frameworks developed for supply chain management often present a more practical approach. For product development, this is still missing. Thus, this thesis suggests developing a method that can be applied as a tool for risk management in product development. The method should explicitly describe steps for the individual phases and should present an approach that can be easily followed. In the following, the requirements and recommendations (REQ) for the method will be derived. The list of requirements can be found in the Appendix (section 9.4.1, p. 110).

REQ 1: The method is a tool for risk management.

REQ 2: The method consists of clear steps that can be easily followed.

In contrast to the risk management frameworks (see section 3.1.2), it is assumed that a method for risk management needs to concentrate on a certain aspect and cannot be as generic as the frameworks. Thus, the decision was made at the beginning of the development that the method will concentrate only on risks that occur within the focal element and the transformation phase. It will not address risks arising from the relationships to customers or suppliers, nor addressing risks that arise outside the element's sphere of influence. It will concentrate on the achievement of the desired outputs in the transformation phase. It is not excluded that the method can be used for other aspects as well. It may be possibly adapted for other focuses (e.g. customer-supplier relationships, schedule risks, external risks, …). However, this might be an issue for further research.

As described before, the evolving product seeks to achieve the specifications, which determine the final product's success. But not every specification is fulfilled by the final solution and some fall behind or are barely followed-up at all. Therefore, the achievement of specifications needs to be explicitly addressed. This will be the focus of this thesis and it is investigated in the context of embodiment design in section 3.3.4.

REQ 3: The method addresses risks of not achieving specifications.

The process frameworks presented impose important recommendations for the method to develop. First, the frameworks propose an approach of five phases identified in the previous section (p. 21). This procedure seems to be highly elaborated since all authors follow more or the less this schema.

REQ 4: The method to develop follows the scheme of the five phases: initialization, identification, assessment and priorization, mitigation, new situation and control.

Looking into the frameworks in more detail, further recommendations can be identified. One of the first activities in the generic frameworks is a trigger that initializes the risk management process. This cannot be fulfilled by a single method, as it always has to be initiated in some kind: e.g. by the management, by an employee or the process regulations of the company. The Munich Methods Model [BRAUN & LINDEMANN 2003, cf. Appendix, p. 113] forms a good framework for choosing the right method and tailoring it to the specific needs of a situation. By considering a methods application, existing conditions have to be taken into account. Furthermore, benefits have to be weighted up against efforts and potential disadvantages. The general advantages and disadvantages of methods are discussed at a later point by means of the FMEA (see section 3.2.1).

Another suggestion derived from the frameworks, is to conduct the method as a team. Except CHRISTOPHER [2003], who describes an assessment on oneself, all others point out the importance of the execution within a team. The basic advantage of an application within a team is the estimation from different points of views. If various perspectives are regarded, cross-functional aspects can be identified which may not be recognized otherwise [LINDEMANN 2006A, p. 23 ff.].

REQ 5: The method emphasizes the application within a cross-functional team.

In the initialization phase, the meeting in which the risk management will be conducted has to be prepared. It is useful to collect necessary information and data in advance, set up a schedule and have a moderator guiding through the meeting.

REQ 6: Activities that have to be conducted in advance for the application of the method are described.

Moreover, means and tools needed should be prepared in advance. In the frameworks presented, some authors provide worksheets, e.g. the self-assessment workbook of CHRISTOPHER [2003], whereas others describe implemented tools only roughly [e.g. NORMANN & JANSSON 2004]. The method to develop should also support the risk management process by means of appropriate worksheets or tools.

REQ 7: Adequate means or tools support the procedure of the method.

Since a variety of perspectives is emphasized, it is also important to align the team's understanding of the analyzed object and to establish a common language. Otherwise misunderstandings might occur and not all potential benefits may be achieved. It is important,

that the scope of the analysis is clear for all participants, as well as the intended objective of the analysis.

REQ 8: The scope and objective of the method are clearly defined.

Additionally, it may be useful that the analyzed object is visualized in an appropriate manner and discussed. All concerns can be clarified by now so that everyone is familiar with the object. This is not a requirement that the method has to fulfill but rather a necessary condition for its application. Otherwise, the best possible results might not be the achieved.

REQ 9: The analyzed object is visualized and presented.

Key elements of the method have to be defined carefully in order to guarantee that all team members have the same understanding of them. Finally, it has to be ensured that the purpose of the analysis is communicated to the participants.

REQ 10: Key elements are described precisely and a common language is established.

All approaches in literature agree that risk management is a proactive approach that anticipates risks rather than simply reacts to occurring problems. And although the tool of HARLAND ET AL. [2003] is initiated by a defined problem, the basic idea of this approach is still proactive. Since processes in Supply Chain Management are repeated, there is a possibility that this event will occur a second time. For example, an interrupted supply in the past may happen again. In product development, the whole process is not repeated for the same product – maybe for similar or derivative products, but not the same one. However, time and cost-consuming iterations should also be avoided in the process of product development.

REQ 11: The method manages risks proactively.

During the identification phase, possible risks are identified and described in more detail. The method should therefore emphasize the identification and description of the risks.

REQ 12: The method identifies and lists the risks of the analyzed object.

Afterwards, the risks have to be assessed. An appropriate manner has to be developed how the method will achieve this regarding the specification risks. The frameworks – as well as the nature of risk – suggest that both the likelihood of occurrence and the potential impact have to be estimated.

REQ 13: The method estimates the probability of occurrence and the impact of each risk.

In order to achieve a manageable set of risks, the risks have to be prioritized and evaluated against each other. Not all frameworks demand that the risks have to be ranked but suggest at least some kind of visualization so that one gets a feeling for the significance of a single risk compared to the others.

REQ 14: The method prioritizes the risks.

The method should then address the phase of mitigation (cf. REQ 4, p. 27). Not only appropriate countermeasures, e.g. prevention or contingency plans, have to be developed. Also responsibilities and a due date for their implementation have to be set.

REQ 15: The method describes mitigation measures.

REQ 16: By means of the method responsibilities as well as completion dates are assigned.

By means of applying the method, a new situation will be achieved. In this phase, the effectiveness of the actions taken has to be estimated.

REQ 17: The method measures the effectiveness of actions taken.

Furthermore, the new state of the risks has to be monitored. If appropriate, an iteration of the risk management process should be initialized.

REQ 18: The method monitors the state of the risks and – if appropriate – suggest the iteration of the process.

Finally, a state is achieved whereas either a desired risk level has been obtained or the process has proceeded so far that there is no need anymore to assess and manage the risks. At this point, they will either have occurred or not. For supply chain management and project management, the need for a continuous risk management is more evident because processes are repeated all the time. In project management, processes may be repeated, e.g. if the project‘s outcome is requested a second time. However, for product development, the same process cannot be repeated – or there is no need because the product has already been developed. Therefore, it should be indicated when a final state is achieved. This represents less a requirement than a general condition for the application of the method. However, it should not be neglected.

REQ 19: The method indicates a final status.

It can be summarized that the procedure of several risk management frameworks follows a similar schema. Requirements have been derived for a method that is suitable to manage risk on a more operational level. The identified phases and the requirements derived seem to be very similar to the methodology of a well-known technique in engineering: the Failure Mode and Effect Analysis. Other methods for risk management do not address all phases but are specified for one phase. For a detailed overview and classification of RM methods see OEHMEN [2005, Table 4-2, p. 82 ff.]. The FMEA was chosen because it can be interpreted as a method for risk management. It follows the five phases, as well as it fulfills the derived requirements in great parts. The method has become a common tool to assess and manage reliability issues in product development. It will be analyzed and discussed in the next section. Further recommendations regarding the method to develop will be derived.

3.2 Failure Mode and Effect Analysis (FMEA)

In this section, the FMEA is presented and analyzed. First, the method is discussed in general regarding its objectives, procedure, effects, as well as advantages and disadvantages (section 3.2.1). Its variants and current application as a tool for quality issues are described (section 3.2.2). It is compared to existing risk management frameworks (section 3.2.3) and its possible application as a risk management tool is discussed (section 3.2.4).

3.2.1 Discussion

The Failure Mode and Effect Analysis (FMEA) is an "analytical technique used by a product design team as a means to identify, define, and eliminate, to the extent possible, known or potential failures of a (…) system" [OTTO & WOOD 2001, p. 565]. It is a well-understood method in engineering and described by many authors [e.g. LINDEMANN 2006A, OTTO & WOOD 2001, PAHL & BEITZ 2006, and STAMATIS 2003]. The possibilities for applying the FMEA are manifold: Different systems can be analyzed, including concepts, designs, processes, or services [STAMATIS 2003].

The first formal FMEAs were conducted in the aerospace industry in the 1960s to address safety issues [MCDERMOTT ET AL. 1996, p. 3]. Since then, the method has been adapted for other fields as well. For example, it has become a widespread tool for quality improvement in the automotive industry because it is part of the quality standard QS-9000 or recommended by other international standards. Moreover, the FMEA is also applied in a variety of other businesses to address quality, reliability, and safety issues in product design [DYADEM PRESS 2000A & B, JOHNSON & KAHN 2003, MCDERMOTT ET AL. 1996, NASA 2000].

Engineers have always analyzed products and processes for potential failures. The FMEA provides a means to standardize this approach and establishes a common language. This does not only optimize the process within a company, moreover it is also helps to align processes between companies [MCDERMOTT ET AL. 1996, p. 3]. Its systematic methodology is a bottom-up approach taking the basic assumption into account that every part of a product or process can and eventually will fail. During its procedure, the FMEA focuses on [DYADEM PRESS 2000A & B, p. 6-1]:

- The recognition and evaluation of potential failures and their effects
- The identification and priorization of corrective actions
- The documentation of these identification, evaluation and mitigation activities.

Possible failures – also called failure modes – are assessed regarding their likelihood of occurrence, the severity of their consequences, and the probability that the failure is detected before the impact of the effect is realized.

The objective of the FMEA is to prevent failures in product design before they occur [DYADEM PRESS 2000A & B, LINDEMANN 2006A, MCDERMOTT ET AL. 1996, OTTO & WOOD 2001, STAMATIS 2003] and especially „before it is to late to do anything about them" [BAXTER 1995, p. 294]. Typically, the FMEA is conducted by a team and the meeting is

prepared and held by a moderator. It is the task of the moderator to guide through the meeting. He is responsible for the compliance of the time table. It is highly beneficial if the moderator is familiar with the method in order to guide reliable through the analysis and to answer questions regarding the procedure. Additionally, he moderates discussions and helps to solve conflicts.

Most authors describe a similar procedure [e.g. MCDERMOTT ET AL. 1996, p. 27 ff., OTTO & WOOD 2001, p. 566 ff.]. A 10-step-approach as shown in Table 3-2 is often suggested.

1.	*Review the analyzed object and list each function of it*
2.	*Identify and list potential failures*
3.	*List potential causes or mechanisms of the failure modes*
4.	*List potential effects of each failure*
5.	*Estimate the severity (S) for each failure*
6.	*Rate the likelihood of occurrence for each failure (O)*
7.	*List current or expected controls/test for detecting a failure* *Assess the detection rating for each failure mode (D)*
8.	*Calculate the Risk Priority Number (RPN) for each failure mode*
9.	*Develop recommended actions for the failure modes* *Assign responsibilities to appropriate parties and team members* *Set a schedule for implementing the actions*
10.	*Implement the corrective actions* *Update the S-O-D ratings and calculate the "Resulting RPN"*

Table 3-1: Procedure of the Failure Mode and Effect Analysis (FMEA)

First, the object of the analysis has to be reviewed to ensure that everyone in the team has the same understanding of it. This can be achieved by means of blueprints, drawings, flowcharts, etc. In a second step, potential failure modes are identified and may be grouped into categories. Useful techniques therefore are brainstorming, interviews, or the Fault Tree Analysis (FTA). For an extensive overview of methods see LINDEMANN [2006A, Appendix] or OEHMEN [2005, Table 4-2] who identifies suitable identification methods from a perspective of risk management.

After having identified the failure modes, their potential causes are identified (Step 3). Each failure mode may have a single cause or several mechanisms that lead to it. In a forth step, the effects of each failure mode are identified including the impact on the analyzed system, the environment, or human users. BAXTER [1995, p. 295] distinguishes between four classes of effects: on a component, on the entire product, on the customer, and beyond the customer.

Having identified the failure causes and effects, the severity and the likelihood of occurrence are estimated (Step 5, 6). Although it is not downright specified, most authors suggest a 1…10 rating for both assessments [BAXTER 1995, DYADEM PRESS 2000A & B, LINDEMANN 2006A, MCDERMOTT ET AL. 1996, OTTO & WOOD 2001, STAMATIS 2003]. It is important to establish a clear and concise description for the scales to ensure that all team members have a

common understanding. If possible, the assessment scale for the occurrence rating can be based on existing failure data [MCDERMOTT ET AL. 1996, p. 27].

In step 7, current or expected controls, which detect the failure before the customer notices it, are identified. The effectiveness of these detection measures is also rated by means of a scale, usually a 1…10 rating. Other classifications may be chosen, but it is important that all assessment scales show the same range. An example for the assessment scales is given in Figure 3-4.

Severity Rating	
1	No effect
2	Very minor (only noticed by discriminating customer)
3	Minor (affects very little of the system; noticed by the average customer)
4/5/6	Moderate (most customers are annoyed)
7/8	High (causes a loss of primary function; customers are dissatisfied)
9/10	Very high and hazardous (product becomes inoperative; customers are angered; the failure may result unsafe operation and possible injury)

Occurrence Rating	
1	No effect
2/3	Low (relatively few failures)
4/5/6	Moderate (occasional failures)
7/8	High (repeated failures)
9/10	Very high (failure is almost inevitable)

Detection Rating	
1	Almost certain
2	High
3	Moderate
4/5/6	Moderate (most customers are annoyed)
7/8	Low
9/10	Very remote to absolute uncertainty

Figure 3-4: FMEA Assessment Scales according to Otto & Wood [2001, p. 567 ff.]

After the severity, the likelihood of occurrence, and the detection rating are assigned, the Risk Priority Number (RPN) can be calculated. This is achieved by multiplying the individual values (see Table 3-2).

Risk Priority Number	=	*Severity Rating*	*x*	*Occurrence Rating*	*x*	*Detection Rating*
RPN		***S***		***O***		***D***

Table 3-2: Calculation of the Risk Priority Number (RPN)

Due to its range from 1 to 1000, the RPN infers linearity. However, it is a discrete means to set two risks in relation to each others. While the RPN remains quite linear for low ratings (1, 2, 3, …), the gaps between the RPN with high ratings get larger and larger (…, 729, 810, 900, 1000). It can be generalized, that the RPN represents a means of comparison rather than an "absolute" value. BAXTER [1995, p. 297] points out that the RPN "represents a simple logic: the risk to the manufacturer, of anything from customer dissatisfaction to product liability prosecution".

The individual failure modes can then be prioritized according to their individual RPN rating. Some authors also suggest calculating the "Total RPN", the sum over all ratings, as a further indicator. It has to be noted that the very believe in the values of the RPN may overestimate or underestimate some risks. For example, high individual ratings may also indicate critical risks although their RPN might be relatively low. The ratings represent subjective assessments and should be critically reviewed. Additionally, a sensitivity analysis might be beneficial to interpret the RPNs in a correct manner [described e.g. by LINDEMANN 2006].

Other teams would probably come to different results for the same analysis. This assumption is based on two scenarios: First, another team might assign different numbers to the individual assessments, but overall the difference between the assessments remains constant: The other team comes to the same conclusions as the first team, but associates different values with its results. However, the proportion would remain the same. For example, the other team might evaluate the occurrence rating constantly one or two points lower. That would change the individual RPNs – but not the ranking of the failures. The second scenario is based on the assumption that the other team has another state of knowledge. Therefore, the evaluation of those risks would differ from the first one. That would change the ranking position of some risks but the conclusions for the rest remain the same.

After the assessment of the failure modes, corrective actions can be developed (step 9). The highest ranked failure modes should be addressed first, but also those with a high severity rating. Sometimes a "critical" RPN is recommended where any failure mode with a higher RPN is attended to. This is decided individually from case to case: The threshold needs to be set according to the impact of the potential failures. Whereas an RPN of 100 may be low for electric devices in households, it would be too high for the operation of a nuclear energy plant. Thus, those thresholds have to be carefully chosen.

Nevertheless, corrective actions address at least one the following intends:

- The reduction of the occurrence of a failure
- The reduction of the impact of a failure's consequences
- The increase of the effectiveness of detection measures.

Developing mitigation actions also includes assigning responsibilities to appropriate parties and setting a completion date. After the recommended actions have been implemented, the individual ratings are updated. As the last step, the Resulting RPN is calculated. There should be a significant reduction in the RPN – or otherwise the actions taken were not effective. As a result, the Total RPN will also decrease. There is no target RPN and failures might always occur. The question is how much risk the team, or the company, is willing to take.

The direct output of the FMEA is a prioritized list of potential failures, a list of potential detection measures, as well as a list of assigned corrective actions with responsibilities and completion dates [STAMATIS 2003, p. 40ff.]. Further benefits derived by the FMEA are a more robust product or process, the reduction of the need for after-the-fact corrective actions and late change crises [MCDERMOTT ET AL. 1996, p. 4].

The FMEA demonstrates other advantages than simply preventing failures. It standardizes the approach to analyze products and processes for potential failures. The benefit is not only a safer product or an increased product quality. The method also helps to reduce costs by identifying improvements early in the development process when changes are relatively easy and inexpensive. This has a direct impact on customer satisfaction – caused by the product quality and lower product costs. Furthermore, the method documents the analysis, corrective actions, as well as responsibilities and completion dates. The Risk Priority Number helps by prioritizing the failure modes and improvement actions. The FMEA can be applied within a team, between different departments or even companies. It establishes a common language, provides means for the communication, and reduces misunderstandings. Furthermore, it is not limited to any type of business, and can be used for design, manufacturing, operations or services.

But the FMEA also shows some disadvantages. Its application requires expertise, experience, and good team skills [DYADEM PRESS 2003A & B, p. 6-7, JOHNSON & KAHN 2003, p. 352]. Without reliable data, the method becomes a guessing game based on opinion rather than actual facts [MCDERMOTT ET AL. 1996, p. 4]. Furthermore, the analysis of complex systems can become difficult, time-consuming and therefore costly. Its most profound disadvantage may be the inability to analyze and detect composite failures. In the automotive supplier industry, JOHNSON & KAHN [2003, p. 348] also point out that the FMEA is often only conducted "pro forma" – in order to placate customers but not to achieve real benefits.

The disadvantages named above are part of the downside of methods in general. In order to guarantee a successful application of methods, some fundamentals have to be regarded. Overall, a method must not be applied for itself, but to solve the underlying problem. The solution of a defined problem should always be in the focus of the application. The mere application of a method does not necessarily solve the problem. The will to achieve certain objectives is crucial for the success of its application. The bottom line is, as VAN WIE ET AL. [2005] point out, that methods should have a positive influence on how teams perform their work.

REQ 20: The method has a positive effect on how the team performs its work.

To apply a method in an appropriate manner, longsome familiarization with it may be necessary. Blind reliance on the suggested steps does not necessarily lead to the desired objectives. Therefore, a method needs to be tailored according to the situation at hand. If this is not considered, the derived results might not be correct.

On the other hand, methods also offer a number of generic advantages. By means of them, a structured procedure can be easily achieved. A concrete and well-defined approach may help to achieve specific results. Best practices can be repeated for other projects as well. Methods also offer a great transparency regarding how decisions have been achieved since most of them document their procedure in an appropriate manner.

If one is aware of possible disadvantages, methods provide great benefits. They help to understand certain characteristics of an object in a better manner [VAN WIE ET AL. 2005]. The FMEA represents a proactive risk analysis technique where potential failure modes are systemically identified before they occur. It supports the team in the development process and

contributes to the creation of customer value. Therefore, it is reasonable that the FMEA can be further adapted for Risk Management as it has been adapted for quality issues.

REQ 21: The method helps to understand characteristics regarding the risks a product faces in a better manner.

Before the method and existing frameworks are compared in section 3.2.3, current forms of its application are briefly described in the next section. This will give the reader an impression about the variety of the method's application

3.2.2 Current Application of the Method

As already mentioned in the previous section, the application of the FMEA is not restricted to a specific object of analysis. In the following, variants of the method are described in more detail and examples for sectors where the FMEA is applied are given.

Different systems can be analyzed in the design and manufacturing process [McDermott et al. 1996, Otto & Wood 2001, Stamatis 2003]. Thus, some variants of the FMEA have been generated. The most common ones are the Design and Process FMEA, described e.g. by Stamatis [2003, p. 40 ff.] who overall identifies four types:

- The **Design FMEA** is a variant used to analyze products before they are released to manufacturing. The focus is laid on failure modes that are caused by design deficiencies.
- The **Process FMEA** analyzes manufacturing and assembly processes. It focuses on failure modes caused by process or assembly deficiencies.
- The variant **System or Concept FMEA** is used to analyze systems and subsystems in the early concept design stage. Potential failure modes between the functions of the system are identified. These are caused by system deficiencies.
- By means of the **Service FMEA**, services are analyzed before they reach the final customer. It aims to identify failure modes caused by system or process deficiencies.

All types follow the generic procedure of an FMEA presented in section 3.2.1. Dependent on the object of analysis, minor adjustments have to be made or individual recommendations may be regarded. For example, it is recommended for Process and Service FMEAs to map the flow of the process (service) by means of flow charts, whereas blueprints are more appropriate for Design FMEAs. For more details, it is recommended to study Stamatis [2003, p. 107 ff.]. The author gives an extensive overview about the FMEA, its variants, and describes each type in detail.

The FMEA was first applied in the 1960s by the aerospace industry to address safety issues. The technique was then adopted in the 1970s by the automotive industry. Since then, the scope of the FMEA has been expanded, not only to address safety but also major quality and reliability issues ([McDermott et al. 1996], [Johnson & Kahn 2003]). It has become a wide spread tool in many fields of engineering, e.g. in the aerospace, the automotive, the electromechanical, or the semiconductor industry. The method is not only applied as a tool for

quality issues. Moreover, the FMEA has recently also been used for product design safety due to the law on corporate responsibility [JOHNSON & KAHN 2003].

Nowadays, the technique has also been discovered by non-engineering sectors, e.g. the health care industry. Since the FMEA represents a general tool to identify possible failure modes in processes, its application is not restricted to product development or manufacturing. WOODHOUSE [2003] points out that health care organizations should select at least one high-risk process annually, in order to identify possible failure modes and effects, and then take steps to reduce or eliminate them. Some examples are the process of crossmatching blood in the laboratory, accessioning specimens into the histology laboratory, or verbally reporting laboratory or pathology results. For a more detailed description see WOODHOUSE [2003]. Further examples in engineering sectors are described by [JOHNSON & KAHN 2003] and [STAMATIS 2003].

In summary, it can be noticed that the FMEA is a very flexible method that can be used for various objects, i.e. products, processes, concepts, and services. It is not restricted to the engineering sector and is also a useful technique in other industries. A reason for this may be the fact that the FMEA is a highly generic and pragmatic approach. The basic assumption – every part of a process or product may and will fail – can be transferred to non-technical sectors as well. Furthermore, the procedure of the FMEA is highly analytical and similar to the risk management approaches presented in section 3.1.2. This will be discussed in more detail in the following section.

3.2.3 Comparison to Existing Risk Management Frameworks

The procedure of the FMEA follows the same scheme the generic risk management frameworks are based on (cf. Figure 3-5). The individual steps of the method can be assigned to the five phases of the risk management frameworks: Initialization, Identification, Assessment and Priorization, Mitigation, New Situation and Monitoring (). The numbers of the steps of the FMEA in the following table are derived from the method's general procedure presented in Table 3-1. Some of the steps of the original ten-step-procedure are divided into subsections, indicated by assigned characters (e.g. 7a and 7b).

In the Initialization phase, it is decided whether the FMEA should be applied. This decision is made either by the team or the management. The reason for its application is often also a mandatory requirement in the process procedure of the company. Before its execution, the meeting in which the FMEA will be applied has to be prepared regarding the people and resources needed. A moderator has to be chosen, as well as the participants of the meeting. Furthermore, the purpose and objective have to be defined and communicated to all participants.

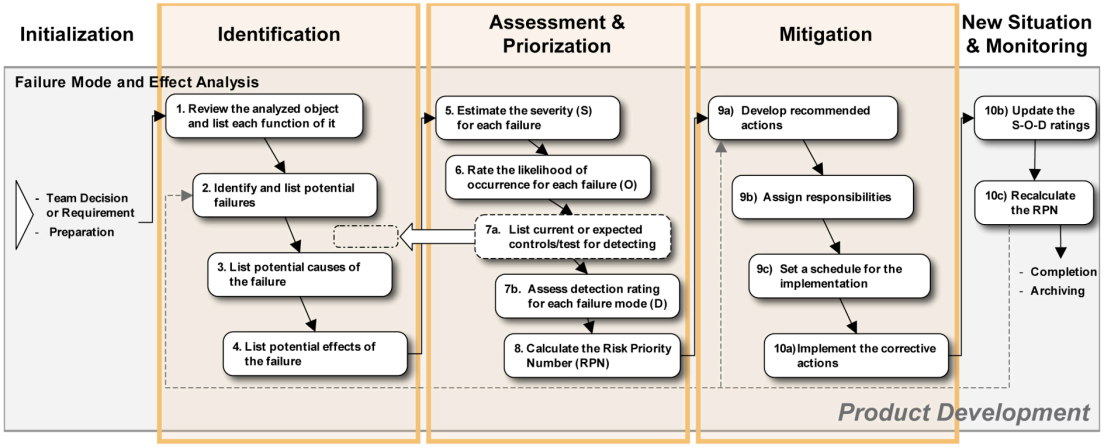


Figure 3-5: The Schema of the Failure Mode and Effect Analysis

Afterwards, the FMEA can be conducted according to the procedure described in detail in section 3.2.1. Steps 1 to 4 form the phase of Identification: The analyzed object has to be reviewed, and potential failures are identified. Causes that may lead to the failure are identified and listed. In the last step, the potential effects of the failure modes are identified and described in more detail.

The steps 5, 6, 7b, and 8 can be assigned to the phase of Assessment and Priorization. The severity and the likelihood of occurrence for each failure mode are estimated (step 5, 6). The procedure of the FMEA then suggests listing current or expected controls and tests to detect the individual failure (step 7a). This step should be attributed to the phase of Identification. It can only be assumed why this is conducted in a later phase: Existing detection measures should not be taken into account for the assessment of the severity and likelihood of occurrence. Within this procedure, the detection measures are not yet identified. Thus, the two ratings – in particular the severity rating – are more objective and it is prevented that the assessment may be influenced subconsciously. After the detection measures are identified, their effectiveness is rated as well (step 7b). This step clearly belongs to the phase of Assessment again. After the individual ratings are assessed, the Risk Priority Number (RPN) can be calculated (step 8). By means of the RPN, the failure modes can be prioritized and ranked against each other.

Steps 9a, 9b, 9c, and 10a form the phase of mitigation. Failure modes with a high individual rating should also be taken into account when actions are developed in step 9a. Furthermore responsibilities are assigned, completion dates are scheduled, and the actions are implemented in the phase of Mitigation.

A new situation is then achieved, and the ratings as well as the RPN can be re-calculated in step 10b and 10c. The updated ratings help to monitor the failure modes. If appropriate, they trigger the development of additional mitigation measures and the identification of new failure modes. Furthermore, the new assessment forms a mean to control the effectiveness of the actions taken. If the team is content with the resulting RPN, the FMEA can be completed. It has to be noted that there is no specific “target RPN” to achieve. In the final step, the FMEA should be archived for two reasons: first, to document the efforts taken to identify and

mitigate potential failure modes of the analyzed object. Second, to help similar projects in the future as a checklist to identify possible failures.

It has been shown that the FMEA follows the same procedure as the different risk management frameworks in product development, project management, and supply chain management. This is not surprising since the FMEA is an analytical and generic technique that has been used in engineering for more than 40 years. Engineers have always analyzed products and projects for potential failures. The FMEA is a matured method that has been developed and optimized over years.

In recent years, the importance and relevance of Risk Management has risen in product development and other industry sectors. Due to factors like global competition, an increasing cost-pressure, and the demand for decreasing development times, uncertainty in product development is rising. It has become more and more important to identify and – if necessary – deal actively with potential risks [BROWNING ET AL. 2002, HARLAND ET AL. 2003, NORMANN & JANSSON 2004, SKELTON & THAMHAIM 2005].

The traditional scope of the FMEA is slightly different: it analyzes systems regarding potential failures and does not address risks in particular. The approach focuses on occurring problems and only address risks in the sense of technical reliability. (Risk and failure have been defined in section 2.3.1.)

Nevertheless, the basic procedure of the FMEA and the risk management frameworks remains the same. The method addresses a large number of the requirements for a practical risk management method identified in section 3.1.3. It follows the five phases identified in section 3.1.2 and also takes "Monitoring" into account, a task that is not considered by every framework presented. The FMEA may form a tool for "horizontal" risk management and does not take a vertical dimension into account. In the reviewed frameworks, this vertical dimension is only mentioned by OEHMEN [2005] and named "Aggregation" of risks. It links the risk management process to a higher level in the company. This may form a sixth phase but will be beyond the scope of a practical risk management method.

In the following section, it will be shown that the FMEA is suitable as a method to manage risks and what modifications have to be made in order to tailor the procedure.

3.2.4 Potential Application as a Tool for Risk Management

The procedure and the phases of the FMEA have been discussed in detail in the previous sections. First, the traditional methodology of the FMEA has been presented in section 3.2.1, its current application in section 3.2.2. In the previous section it has been shown, that the basic procedure of several risk management frameworks follows the same scheme the FMEA is based on. This section will discuss the potential application of the FMEA as a practical step-by-step method for risk management.

PECK ET AL. [2003, p. 60] mention a potential application of the FMEA for supply chain failures in the appendix. OEHMEN [2005, p. 88] also states the potential of the FMEA as a risk management tool. However, a concrete application is not presented. Thus, a small experiment was conducted with data derived from a field study in Supply Chain Management. The field

study was a research project of the ETH Zurich in cooperation with the HSW Lucerne in 2006. In the original procedure, the approach of ZIEGENBEIN & SCHNETZLER [2005] was applied to assess risks in the supply chains of four Swiss enterprises.

In the experiment for this thesis, a methodology based on the FMEA was applied. Two modifications have been made: First, the term 'failure' was replaced by the word 'risk'. Second, the method was applied in a "lean" way. While the FMEA suggests identifying every possible failure, it was suggested to analyze only risks identified by a team of experts. Table 3-3 shows the modified approach used in the experiment. The second column lists the individual steps of the modified FMEA. The column on the right identifies the correlating phases according to the scheme the risk management approaches described in section 3.1.2 follow.

1.	*Review the analyzed object and list each function of it*	Identification
2.	*Identify and list potential risks*	
3.	*List possible potential causes or mechanisms that may lead to the risk*	
4.	*List potential consequences of the risk*	
5.	*Estimate the severity of the consequences (S) for each risk*	Assessment
6.	*Rate the probability of occurrence for each risk (O)*	
7.	*List current or expected controls/tests for detecting the risk* *Assess detection rating for each risk (D)*	Identification
8.	*Calculate the Risk Priority Number for each risk: RPN = S x O x D*	Assessment / Priorization
9.	*Develop recommended actions for the risks* *Assign responsibilities to appropriate parties and team members* *Set a schedule for implementing the actions*	Mitigation
10.	*Implement the corrective actions* *Update the S-O-D ratings and calculate the "Resulting RPN"*	Mitigation, New Situation & Monitoring

Table 3-3: First Modified Approach for Risk Management based on the FMEA

If the FMEA is applied as a tool for risk management, some modifications have to be made. The "traditional" FMEA is based on the three columns of occurrence, severity, and detection rating. These figures have to be "translated" into the corresponding equivalents in risk management.

The likelihood of a failure's occurrence can be "translated" into the probability of occurrence for a risk. The difference between failure and risk has been defined in section 2.3.1. Whereas

a failure is an issue that will happen and it is not sure how often it will occur, a risk is an event with an uncertain probability of occurrence. And although the FMEA refers to "likelihood of occurrence" in the sense of the potential frequency of a failure, it is reasonable that the equivalent in risk management is the risk's probability of occurrence.

The severity of a failure is the equivalent to the severity of a risk. The FMEA regards the effects on the product and on the end customer. In Project Management and Supply Chain Risk Management, an emphasis is laid on the reaction of the customer and the impact on the focal company's costs. In all approaches, the severity rating assesses the consequences of a failure or respectively a risk.

By means of the detection rating, the FMEA assesses the ability to detect the failure within the given time and resource limits. For risk management, this would mean the ability to detect the occurrence of a risk. The modified assessment scales for the occurrence, severity, and detection rating are shown in the Appendix of this thesis. For all three scales, a 1…10 rating was chosen as proposed in most of the literature regarding the FMEA. The 1…10 ratings and potential disadvantages are discussed in section 3.2.1. Such scales accommodate a simple estimation while still providing an adequate range for comparison. Disadvantages, e.g. apparent linearity or objectivity, can be compensated by the awareness of the experienced user, a critical review of the assessments, or a sensitivity analysis.

REQ 22: The assessment is conducted by means of 1…10 scales.

Afterwards, the experiment was conducted by means of the above-presented modified FMEA. Due to the huge amount of data, not every supply chain or all identified risks have been assessed with this approach. Only one supply chain from the field study was re-analyzed regarding its risks on the supply side. Nevertheless, some fundamental insights could be gained from this small experiment. The procedure of the FMEA and the approach of ZIEGENBEIN & SCHNETZLER [2005] are highly similar. The approaches were so similar, that it seemed as if the risk management framework has re-invented the FMEA or as if it was derived from this matured method. Not only the procedure seemed to be the same, also the results have been consistent. After the experiment, it was shown that the FMEA and various other risks management frameworks follow a similar procedure (cf. sections 3.1.2, 3.2.3).

In general, the application of the FMEA in the experiment worked well. But there were problems with the detection rating. One reason can be assumed for this problem: The occurrence of a risk follows a binary dimension – either it occurs or not. Therefore consequences result for the detection rating. There is no range in the detection of a risk, since it is not a frequent event but occurs only once. It will be detected with certainty, at least when it occurs. The overall objective of all risk management approaches is the detection of potential risks while still enough time is left to respond, before the risk occurs and its consequences are realized. Therefore, this step in the FMEA forms an unnecessary iteration of the overall approach. For further experiments, it can be eliminated.

From another perspective, the detection rating suggests an improvement for risk management. The detection rating of a failure estimates the probability that it is detected before the failure reaches the final customer and therefore is mitigated. In risk management, that would refer to

the effectiveness of existing mitigation measures. This is not taken into account by all existing risk management frameworks but seems highly reasonable.

REQ 23: The effectiveness of existing mitigation measures is taken into account.

The former detection rating should now estimate the ability to control or deal with the risk within a given time frame and resource limits. It is important, that this will be assessed after the severity of a risk has been assessed. Then, it can be assured that the severity rating is as objective as possible.

The small experiment showed that the FMEA is highly suitable as a practical method for risk management. It forms a step-by-step approach that is easy to understand and easy to follow. Furthermore, it is a well-understood method in product development and it is very likely that it fulfills the requirements for a practical risk management tool derived in section 3.1.3. Therefore it is reasonable that the FMEA can be adopted as a method for risk management and also helps to anticipate risks in product development.

Since this is still a very broad definition of the scope, this thesis will investigate the possibilities of its application in early phase of product development. The method to develop may also be suitable for other phases in product development, but needs to be tailored as circumstances demand. However, for the thesis at hand the phase of embodiment design was chosen, since decisive decisions are made and it is crucial for the later success of the product.

REQ 24: The method is customized to the phase of embodiment design.

The characteristics of this phase and possible occurring risks will be presented and discussed in the next section.

3.3 Embodiment Design

This phase of product development will be described and discussed in the following. First, the terminology is introduced and a brief overview over embodiment design is given (section 3.3.1). The necessary input, as well as the objectives this phase seeks to achieve, is presented in section 3.3.2. Afterwards, the procedure is described in detail and the output of embodiment deign is presented (section 3.3.3). Finally, the characteristics of this phase are discussed from a perspective of risk management (section 3.3.4).

3.3.1 Basic Characteristics

"Embodiment Design" is a term coined by PAHL & BEITZ [2006, p. 65 ff.]. It describes the phase between the Conceptual and the Detail Design phase. The objective of embodiment design is – briefly summarized – the development of a "rough layout" of the later product.

Other authors in product development also describe this phase using slightly different terms. E.g. ULRICH & EPPINGER [2003, p. 9 ff., p. 184] describe this phase as part of the system-level design. OTTO & WOOD [2001, p. 535 ff.] refer to it as "Concept Embodiment". This thesis adopts the term "Embodiment Design" since this will make a clear distinction between the conceptual phase, the rough design phase (in which the architecture is determined), and the detail design phase.

After a concept for a working principle has been chosen in the Conceptual Design phase, the concept has to be "embodied". Starting from this principle solution, the physical layout of a technical system has to be defined [BAXTER 1995, PAHL & BEITZ 2006]. The concept is elaborated in more and more detail into a physical layout, the product architecture.

During the development process of the product architecture, decisions are made about the configuration of components, their geometrical layout, material selection, and other issues. Therefore, preliminary layouts are produced. By means of them, it is possible to obtain a broader knowledge about the advantages and disadvantages of the different variants. Many details have to be clarified, confirmed or optimized [PAHL & BEITZ 2006, p. 199 ff.].

The completion of the Embodiment Design phase is then the specification of layout. The layout or product architecture is developed to the point at which a full working prototype is – or could be – made [BAXTER 1995, p. 293]. This forms then the basis for the phase of Detail Design [PAHL & BEITZ 2006, p. 68].

In the following sections, the input and objective (3.3.2), as well as the procedure and the output (3.3.3) of the Embodiment Design are described in more detail. This helps the reader to understand the characteristics of this phase when it will be discussed in section 3.3.4.

3.3.2 Input and Objective

As already mentioned in the previous section, the phase of Embodiment Design follows the Conceptual Design. Thus, the input of Embodiment Design is the chosen concept or principle solution [PAHL & BEITZ 2006, p. 183]. Furthermore the product specifications – identified and elaborated at the beginning of the product development process – represent another important input.

Whereas in the phase of Conceptual Design a variety of uncertainties still exist, the product architecture will be more and more defined and specified now. During Embodiment Design, the emphasis is laid on determining construction structures of the individual assemblies and parts. The objective is the concretization of the principle solution and the specification of the layout [PAHL & BEITZ 2006, p. 384].

3.3.3 Procedure and Output

The procedure in Embodiment Design is described in detail by PAHL & BEITZ [2006, p. 200 ff.]. They suggest an approach following fifteen steps (see Figure 3-6). It may not be always possible to follow this procedure strictly. Some steps have to be performed simultaneously, repeated on a higher level of information, and changes in one area may influence other areas as well. The approach therefore has to be regarded as a generic guideline or as a checklist for the tasks to accomplish.

As described in the previous section, the procedure begins with a concept, the principle solution chosen in the Conceptual Design phase. The process of Embodiment Design itself can be divided into three phases (see Figure 3-6):

- Preliminary layouts and form design
- Detailed layouts and form design
- Completion of checks.

In the first phase, the embodiment determining requirements are identified. They are derived from the list of requirements and contain size-, arrangement or material-determining demands. By means of them, scale drawings of spatial constraints are produced. Assemblies and components fulfilling the main function of the design (also called main function carriers) are identified afterwards. Preliminary layouts and form designs are developed for the embodiment-determining main function carriers. Therefore, the general arrangement, the shapes, and the material of components are determined provisionally. It is recommended to work out selected areas and combine them into several versions of preliminary layouts. After the layouts have been elaborated, one ore more suitable preliminary layouts have to be selected. For the selected layouts, the remaining main function carriers are considered. They have been postponed because existing solutions are known or they have not been embodiment determining until now.

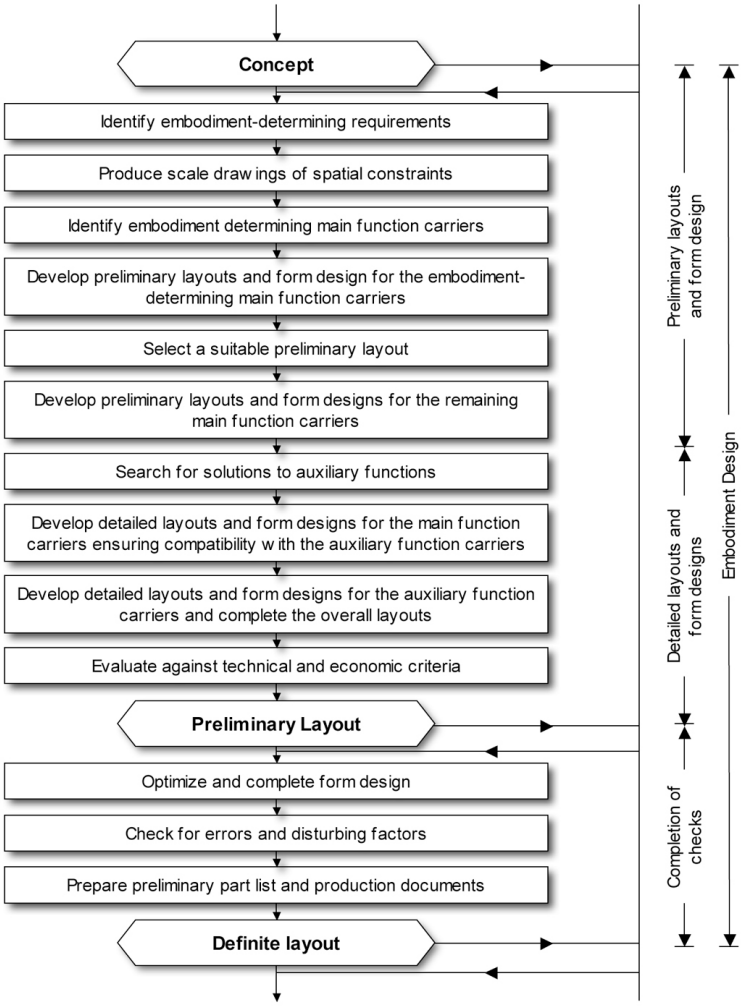


Figure 3-6: Steps of Embodiment Design (derived from [Pahl & Beitz 2006, Fig. 7-1])

In the phase of "Detailed layouts and form designs", the auxiliary functions (e.g. support, retention, or cooling) are determined. Again, if possible, known solutions should be taken into account. This will reduce development time and costs. The detailed layouts and form designs are further developed in accordance to the embodiment design rules. The rules regard several domains, e.g. function, safety, ergonomics, or maintenance [for the whole checklist see PAHL & BEITZ 2006, p. 205 ff., Fig. 7-3]. It has to be ensured that the chosen auxiliary function carriers are compatible with the main function carriers.

Afterwards, standard and bought-out parts are added to the auxiliary function carriers. If necessary, the design of the main function carriers is refined and all function carriers can then be combined into overall layouts. The layouts have to be evaluated against technical and economic criteria, and compared against each other. It is suggested therefore that all preliminary layouts show the same level of detail. As a last step of this sub-phase, one overall layout has to be chosen.

In the phase of "completion of checks", weak points are eliminated. This step optimizes the form design of the chosen layout. The layout design is analyzed for faults in function and effects of disturbing factors. Furthermore, a preliminary parts list, production and assembly documents are generated in this phase. In a last step, the definitive layout is fixed. The authors point out that objectives regarding quality and cost must be achieved by now.

Briefly summarized, the outputs of Embodiment Design are three items: First, a specified layout or product architecture. Second, a preliminary parts list. And third, preliminary production and assembly documents. They will be passed to the Detail Design phase, where the final arrangements, forms, surfaces of all individual parts will be specified and laid down. Drawings, details, cost calculations, and production documents will be elaborated and the final, overall solution is achieved.

In this chapter, the procedure and outputs of Embodiment Design have been described. This and the previous two chapters give the reader the basic information necessary for the next section where the procedure of Embodiment Design is discussed.

3.3.4 Discussion

The phase of Embodiment Design is crucial for the development of the product architecture. Whereas in the phase of Conceptual Design a various number of uncertainties still exist, important decisions are now made and several aspects have to be determined. This section discusses Embodiment Design from a perspective of Risk Management and shows which risks might occur in this phase of product development. For the fifteen steps of Embodiment Design, six types of risks could be identified:

- Risk of lack of information
- Risk of not meeting specifications
- External risks due to suppliers, regulations etc.
- Risk of quality and reliability issues
- Production risks
- Other risks

"Risk of lack of information" is a very generic type of risk. Since information is the processed good in product development, this risk might occur in all phases of the product development process. However, it might also occur in the phase of Embodiment Design and should not be neglected therefore. For all steps in Embodiment Design it is important that the information needed is available. A lack may lead to cost-consuming waiting times and impedes the creation of customer value.

Risks regarding not achieving specifications may occur at the beginning of Embodiment Design, particularly during the first seven steps (see Figure 3-6). In the first step ("Identification of requirements"), reasons for this might be that some specifications are not up-to-date, that important requirements are missing, or that there is a lack of information about the embodiment determining issues. When the main functions carriers are identified and

a first rough layout is derived (steps 3, 4), the risk exists that not all requirements might be fulfilled by this layout. An emphasis is laid on the embodiment determining specifications, but other specifications might fall behind. The consequences might be that the product does not achieve the desired state and does not achieve as much customer value as its potential suggests. That also interferes with the paradigm of perfection in Lean Product Development (see section 2.2): Activities should concentrate on the continuous improvement and involvement of all parties. "All parties" cannot only be interpreted as all resources but also as all specifications.

At this point, step 4 and 5 – the development and selection of preliminary layouts – are the most critical ones. Too little information about the layouts may result in the problem that specifications cannot be achieved. The risk exists that decisions are made in favor of a design that does not fulfill all specifications. Then, remaining function carriers are considered in step 6. They have been postponed because existing or standardized solutions are known. The standardized solutions might not work with the developed function carriers. If standardized solutions do not work with the design as intended, expensive rework might be necessary. Thus, resources and time would be wasted – a contrary to the lean philosophy. This risk belongs to the category "other risks". The type is listed due to reasons of completeness: it is the classification for risks not belonging to any of the other categories. A good example can be derived from the electronic industry. If a company chooses a component type that will phase out (e.g. digital signal processors), the intended maintenance and repair service for the developed product may not be guaranteed. Due to the dynamic nature of electronic technology and markets, it is especially difficult to predict future developments in this industry sector.

In step 9 ("Develop layouts for the auxiliary function carriers and complete the overall layouts"), standard and bought-out parts are added to the existing function carriers. Thus, external risks might come into play. The supply of those parts has to be ensured and, if appropriate, further sources have to be evaluated or alternative solutions have to be developed. Furthermore, the emerging product should fulfill all required rules and legal regulations. If it does not fulfill them, the product might not get the allowance for trading or improvements may be necessary. In the worst case, all development time and resources would be wasted. Again, this is contrary to Lean Product Development, which emphasizes the reduction of waste and an early verification of designs regarding feasibility. More external risks can probably be identified, but this would go too far and is beyond the scope of this thesis.

The risks of quality and reliability issues are more likely to occur in a later phase of Embodiment Design. After a preliminary layout has been chosen (step 11), the design becomes concrete enough to identify potential quality and reliability issues. When the preliminary layout is analyzed for possible faults and disturbing factors (step 12, "Optimize and complete form design"), the Design FMEA in its traditional form may be applied.

Additionally, the Process FMEA might also come into play in the next step. After the generation of production documents (step 14), potential production and assembly risks may be identified. Other methods might be suitable as well and the tool to apply has to be carefully

chosen. However, it should only be shown that production risks may already be identified during the product development process.

In summary, several risks may occur in this phase of value creation. Their severity ranges from minor occurrences with little rework to major consequences where development time and budget may be wasted completely. Six types have been identified and described in this section. Describing the procedure of Embodiment Design, PAHL & BEITZ [2006] also mention potential problems, of course. They point out that it may appear that this or that requirement cannot be met, or that certain characteristics of the chosen concept are unsuitable. If this is discovered during the embodiment phase, they suggest re-examining the procedure adopted in the conceptual phase [PAHL & BEITZ 2006, p. 203]. But iterations are time and cost consuming and should therefore be avoided. The widely accepted "rule of 10" describes that the elimination of failures, and therefore also iterations, becomes more and more expensive the farther the process has proceeded [LINDEMANN 2006A]. Regarding occurring problems, SKELTON & THAMHAIN [2005] state that teams may try to correct them by making expensive or complicated modifications to the product but that it is already too late to improve product design or product performance significantly. In contrast, Lean Product Development emphasizes and early verification of the feasibility of designs and seeks to minimize unnecessary iterations in the development process.

Therefore it is crucial to detect potential deficiencies or specifications that might not be met as early as possible. However, no methodology or tool is described in literature to analyze the preliminary layouts in Embodiment Design. Thus, the method should concentrate on risks of not achieving product specifications.

3.4 Interim Summary: FMEA as a Tool for Risk Management in Embodiment Design

Three aspects have been discussed in this chapter. The characteristics of risk management (section 3.1), its similarities to the fundamentals of the FMEA (section 3.2) and the need for a tool to identify and prevent deficiencies in the phase of embodiment design (section 3.3).

The FMEA is a systematic approach to analyze objects and implement corrective actions and controls. Since this method has been elaborated over years, it has become a standard and is a highly accepted method in engineering. For product development, the guiding frameworks of this thesis – the Munich Procedural Model and Lean Product Development – strongly emphasize the minimization of risks and preventive actions in an early phase of design.

Although various frameworks for risk management exist (see section 3.1.2), a practical and reliable method for its execution is still missing. And the FMEA presents a promising solution for this lack.

Its approach is highly similar to the risk management frameworks and also follows the five phases identified for them (section 3.2.3). The method3.1.3 fulfills most of the requirements for a risk management method derived in section 3.1.3. Moreover, the FMEA even exceeds certain requirements with its detailed description, e.g. it suggests the application of 1…10 scales for the assessment phase. As the risk management frameworks demand, the FMEA also addresses objectives regarding a reduction of the probability of occurrence, a reduction of the impact of a risk, as well as an increase of detection measures.

The output of a method then is not only a number of potential deficiencies, but also a prioritized list that identifies the key challenges the development team will face. The structured approach of the FMEA helps the team to come up with corrective actions, assigned responsibilities and completion dates. This results in a reduction of after-the-fact corrective measures and thus lowers cost early in the process. Thus, the method directly impacts and creates customer value by lowering development costs and achieving a more affordable product. Summarized, a possible adaptation of the FMEA as a tool for risk management early in the design process is indeed possible.

In embodiment design, various decisions affect costs, schedule and performance of the later product. Thus, the application of a method preventing deviations from the target specifications may achieve significant benefits. Moving and adapting the FMEA farther up the development process seems highly reasonable. Then, the procedure of the method can be used to anticipate deficiencies in product development and prevent them effectively.

4 Development of the Approach

This chapter describes the development of the Specification Risk Analysis. Section 4.1 gives a brief overview of the requirements derived in the previous chapter. Afterwards, potential focuses of the method are discussed and the decision is made to concentrate on product performance aspects (section 4.2). An overview of the proceeding of the development is presented in section 4.3. The first draft of the later method is also described in this section. Section 4.4 discusses the derivation of the assessment categories and scales, since this was one of the most significant changes in the FMEA. The incorporation of the remaining requirements is then described in section 4.5. The chapter is rounded off by a brief summary (section 4.6).

4.1 Requirements for an FMEA-based Method for Risk Management in Embodiment Design

While Risk Management, the FMEA, and Embodiment Design were analyzed, requirements have been derived (see chapter 1). Overall, 24 requirements could be identified. They describe the objectives the method needs to achieve as well as conditions that allow a successful application. The requirements are also listed in the Appendix (p. 110).

The most fundamental requirements are that the method should be a proactive tool for risk management – in order to address risks of not achieving specifications (*REQ 1, REQ 3, REQ 11*). Furthermore, the method will be customized to analyze the product architecture elaborated in the phase of Embodiment Design (*REQ 24*). To guarantee a simple but effective procedure, the method should consist of simple steps and follow the five phases: initialization, identification, assessment and priorization, mitigation, new situation and control (*REQ 2, REQ 4*).

In the initialization phase, activities that need to be prepared in advance have to be described (*REQ 6*). It is important to choose participants of the meeting carefully in order to guarantee a cross-functional perspective (*REQ 5*). Additionally, adequate tools to support the procedure of the method should be provided (*REQ 7*). To achieve an efficient meeting, the scope and objective need to be clearly defined and communicated to all participants (*REQ 8*). Participants should understand that the method seeks to improve the understanding of the product architecture, especially regarding the risks it faces (*REQ 21*). Furthermore, the method should have a positive effect on teamwork (*REQ 20*), for example by encouraging team members to express their concerns.

In the identification phase, the object needs to be visualized and presented in an appropriate manner. That guarantees that all participants have the same conception in mind (*REQ 9*). The key elements of the method have to be described precisely and a common language needs to be established (*REQ 10*). The risks should then be identified and listed (*REQ 12*).

For the assessment, the method will estimate the probability of occurrence as well as the impact of each risk (*REQ 13*). Similar to the procedure of the FMEA, this will be achieved by means of 1…10 scales (*REQ 22*). It is important that not only the likelihood and severity are considered but that also previous mitigation measures are taken into account (*REQ 23*). After the assessment, the risks should be prioritized in an appropriate manner (*REQ 14*).

By means of the priorization, it can be estimated which risks need to be tackled first. Thus, the method gives guidance to develop mitigation measures for the most severe risks (*REQ 15)*. It should also assist in assigning responsibilities as well as completion dates (*REQ 16*). Additionally, the method needs to provide means to measure the effectiveness of corrective actions taken (*REQ 17)*. It should measure if the risk level decreases or if further activities are necessary (*REQ 18*). This also implies that the method indicates a final status and the achievement of a satisfactory situation (*REQ 19)*.

These requirements have been derived simultaneously during the literature review and interviews with researchers at MIT (see sections 3.1.3, 3.2.1, 3.2.4). They formed a starting point from which the method could be developed. Not all requirements were expressed that precisely from the beginning on. They have been continuously refined and updated during the development of the overall approach. In order to get a better understanding about the development, decisive decisions are described in the following two sections.

4.2 Potential Focus on Process or Product Related Risks

The FMEA was compared to existing risk management frameworks and similarities were identified. A small experiment with data from a research project for supply chain management was conducted (section 3.2.4). It showed the potential of the FMEA as a risk management tool. The crucial question was if the FMEA could be modified to identify and manage uncertainties in an early phase of product development.

The essential requirements for this tool are summarized in the previous section. Afterwards, a draft for a risk management concept was formulated based on the FMEA. This first approach was tested with data of MIT's course "Product Engineering Processes" [MIT COURSE 2.009 HOMEPAGE 2006]. In this course, senior undergraduate students develop and design a product in groups of about 15 students. Difficulties arose because the author was not part of the development teams and did not get to know the team members. The projects were completed in December 2006 and thus, there was no reason given anymore to conduct a risk analysis. It was challenging to get the necessary data simply by reviewing the team's homework assignments. Nevertheless, two profound insights could be derived: The method could either concentrate on risks related to the process of product development or on risks related to the product itself.

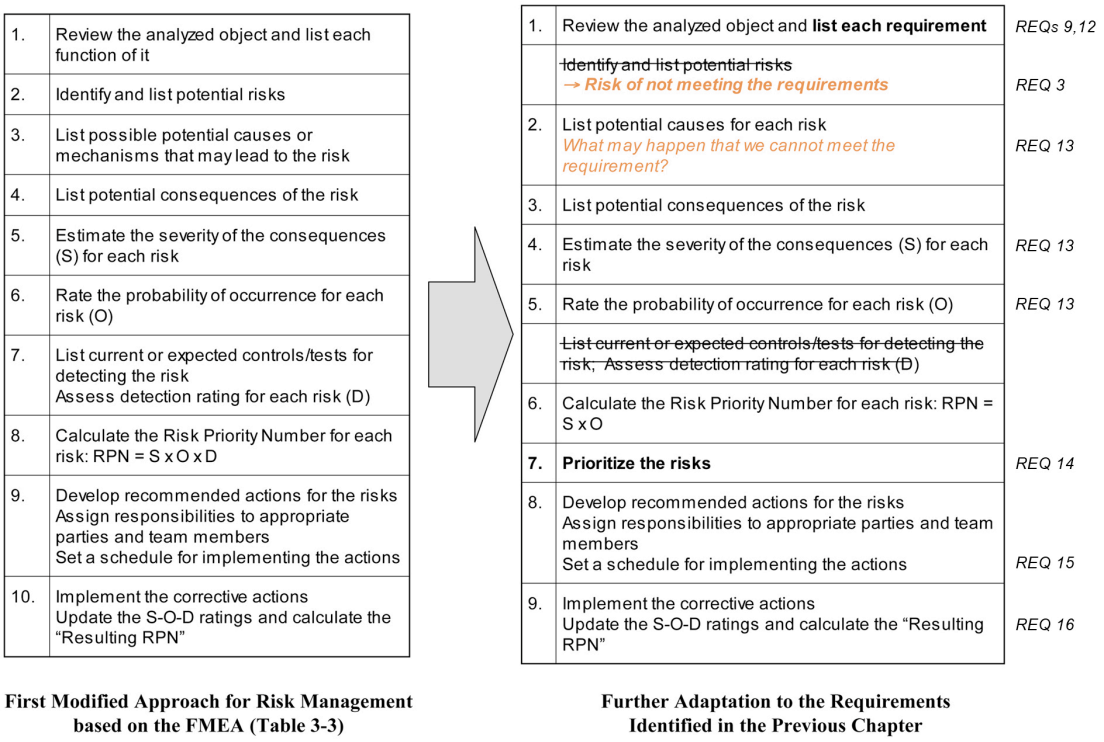
CARBONE & TIPPETT [2004] present a methodology to manage project risks, which they call "Project Risk FMEA". This approach shows potential for a successful adaptation as a risk management tool in product development processes, although probably modifications might be necessary. For risks regarding the product performance, no such tool is described in literature. Thus, the decision was made to concentrate on risks regarding this area. The study

in the automotive industry, which was described earlier in section 2.3.3, enhanced the need for such a tool (cf. REQ 3, p. 26).

The performance of a product is indicated by its requirements defined at the beginning of the development process. Or to be more concrete: to what intent these requirements are met. This leads to the conclusion, that the method to develop will concentrate on product performance and risks of not meeting requirements. It would also be interesting to follow up the approach of managing risks related to the product development process. However, this would have led to a second thesis and in the following, only the product performance risks will be pursued.

4.3 Development of the Methodology

At the beginning, a slightly modified procedure was derived from the variant applied in the supply chain experiment (p. 38). This approach draft is shown again on the left hand side of Figure 4-1. It formed the basis for the development of the risk management tool (REQ 1). Then, the decision was made to concentrate on the achievement of the desired product performance (REQ 3). On the right hand side of Figure 4-1, the first draft of the method to analyze risks of not achieving requirements is shown. The requirements the individual steps seeks to achieve are presented on the right side.



1.	Review the analyzed object and list each function of it
2.	Identify and list potential risks
3.	List possible potential causes or mechanisms that may lead to the risk
4.	List potential consequences of the risk
5.	Estimate the severity of the consequences (S) for each risk
6.	Rate the probability of occurrence for each risk (O)
7.	List current or expected controls/tests for detecting the risk Assess detection rating for each risk (D)
8.	Calculate the Risk Priority Number for each risk: RPN = S x O x D
9.	Develop recommended actions for the risks Assign responsibilities to appropriate parties and team members Set a schedule for implementing the actions
10.	Implement the corrective actions Update the S-O-D ratings and calculate the "Resulting RPN"

First Modified Approach for Risk Management based on the FMEA (Table 3-3)

1.	Review the analyzed object and **list each requirement**	*REQs 9,12*
	~~Identify and list potential risks~~ *→ Risk of not meeting the requirements*	*REQ 3*
2.	List potential causes for each risk *What may happen that we cannot meet the requirement?*	*REQ 13*
3.	List potential consequences of the risk	
4.	Estimate the severity of the consequences (S) for each risk	*REQ 13*
5.	Rate the probability of occurrence for each risk (O)	*REQ 13*
	~~List current or expected controls/tests for detecting the risk; Assess detection rating for each risk (D)~~	
6.	Calculate the Risk Priority Number for each risk: RPN = S x O	
7.	**Prioritize the risks**	*REQ 14*
8.	Develop recommended actions for the risks Assign responsibilities to appropriate parties and team members Set a schedule for implementing the actions	*REQ 15*
9.	Implement the corrective actions Update the S-O-D ratings and calculate the "Resulting RPN"	*REQ 16*

Further Adaptation to the Requirements Identified in the Previous Chapter

Figure 4-1: First Draft for the Risk Management Method

First, the method was customized to analyze product requirements. Step 1 was modified to review not only the analyzed object but also the list of requirements (REQ 3). The second step

has become redundant since the method will concentrate on risks regarding requirements. The identification of risks would simply be the negotiation of the requirements. Thus, this step was not explicitly part of the procedure anymore.

The steps regarding the assessment of the probability and severity were retained (REQ 13). Adapted for requirements, the question needs to be answered, what may happen that the requirement cannot be met and how severe are the consequences (REQ 12).

As experienced in the small test before (see section 3.2.4), the step of detection was eliminated. The whole methodology was tailored to detect and identify risks. The step would have represented an unnecessary iteration of the overall objectives of risk management itself. Instead, the priorization of risks was introduced since this was not explicitly addressed in all descriptions of the FMEA (REQ 14).

The steps for mitigation ("Development and assignment of corrective actions") as well as monitoring ("Update the ratings") remained (REQs 15, 17). They form a very thoughtful approach and seemed to be highly elaborated.

The procedure presented in this section formed the basis for the development of a method to manage product performance risks. It was continuously refined based on small experiments and interviews. A major change was made in the assessment phase: New assessment scales were introduced to estimate the likelihood and severity of requirement risks (REQ 13). They will be presented in the next section.

4.4 Refinement of the Assessment Phase

In order to customize the method to risks of not achieving requirements, the assessment phase was refined. Three new categories were introduced to analyze these risks in a better way. The FMEA suggests that the likelihood of occurrence as well as the severity of a potential risks are estimated by means of 1…10 scales. This way of assessment was also used for developing the method (REQ 21).

How likely the analyzed product architecture will meet the requirement can be assessed by means of two dimensions (see Figure 4-2). First, it has to be estimated whether enough information was collected to answer this question. Second, an estimation of the candidate architecture's technical feasibility indicates whether the analyzed object will meet the requirement or not.

In the following, the term 'requirement' will be narrowed down to 'specification'. This anticipates a decision that was made later during in the field study, which will be presented in chapter 6. Specifications were chosen because they are more explicit and provide less room for interpretation. It is reasonable to introduce this change now because the next chapter will present the latest version of the method and the assessment phase was adapted to specifications as well.

If additional information needs to be collected, the question is "How difficult or uncertain it is to get?" The uncertainty to get the information needed is referred to as accessibility. The more difficult it is to get the information, the more likely the risk occurs, that the specification

cannot be met. The second dimension is called feasibility. The feasibility estimates the capability of the architecture to meet the specification. This is a subjective estimation based on one's engineering knowledge.

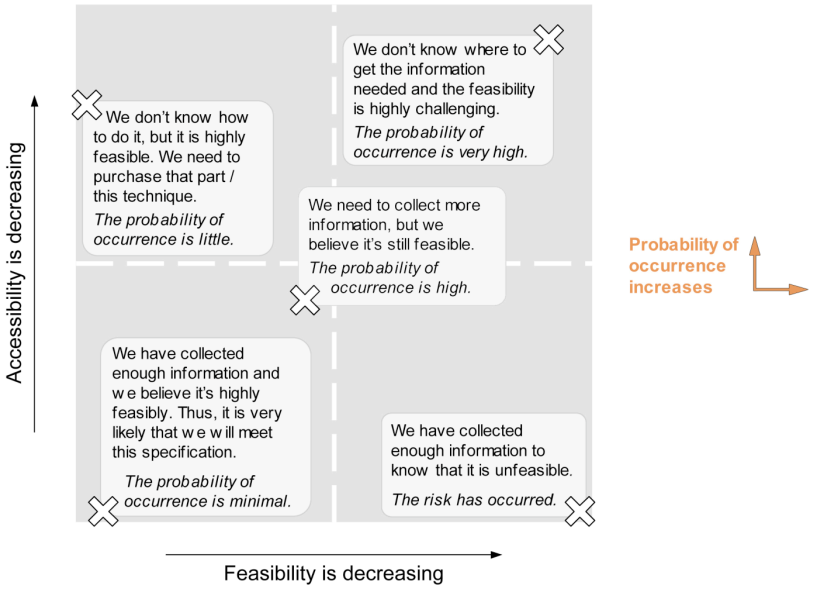


Figure 4-2: Probability of Not Meeting a Specification

In Figure 4-2, five examples of potential constellations are presented in order to enhance a better understanding between the interactions of the two dimensions. Starting from the bottom left, the occurrences will be briefly explained clockwise. For the first one, enough information has been collected and the feasibility is estimated as very likely. Thus, the overall probability of the risk's occurrence is minimal. For the second example, it is difficult to collect the information needed. Nevertheless, the feasibility is estimated as very likely. This estimation may be based on one's engineering knowledge or the fact, that various comparable products meet the considered specification. Thus, the probability is little that the specification cannot be met. But probably some third party product or know-how has to be purchased.

The third example is located in the middle of the figure. Additional information needs to be collected and the difficulty to get the information is relatively high. The feasibility is estimated to a similar extent. Thus, the overall probability that the specification might not be met is high. For the example in the top right corner, it is almost impossible to get the information needed while the engineering experience suggests that the feasibility is highly challenging or almost impossible, too. This indicates that the risk occurs almost certain (very high probability of occurrence).

The last example is located in the bottom right corner. Whereas enough information has been collected, the feasibility is still estimated as impossible. This leads to the conclusion, that the risk has occurred and the specification cannot be met. This example represents a special case in the figure. Strictly speaking, it is not a risk anymore but has become a problem, an occurred risk.

The figure gives an overview how the probability of the risk's occurrence depends on the accessibility of information and the feasibility of the chosen architecture. Note that risk is considered exclusively in the context of not meeting product specifications. With a decreasing accessibility, it is more and more difficult to get the information needed to achieve this product specification. Thus, the probability of the risk's occurrence is increasing. Additionally, with a decreasing feasibility, the engineering knowledge suggests that it is more and more challenging to achieve the specification. As a result, the possibility of occurrence is increasing, too.

One requirement for the method *(REQ 22)* suggests assessment scales of a 1…10 range. This distribution was chosen according to the scales of the FMEA described e.g. by [OTTO & WOOD 2001]. The developed scales for the risk management are shown in the following tables. For the accessibility rating, five levels were defined to estimate the difficulty or uncertainty to get the information needed (see Table 4-1). Starting from a low rating (1), where enough information has been collected, the scale ranges to a high rating (9/10) indicating that no information is currently available. The ratings in between represent an increasing uncertainty: The higher the rating, the more difficult is it to get the information needed. For example, a medium rating indicates, that some information has already been achieved but it is not sufficient. Additional data needs to be collect, but it is difficult to get.

Rating	*Verbal description*	
1	Very high state of knowledge	Enough information has been collected.
2/3	High state of knowledge	Additional information has to be collected, but it is available.
4/5/6	Medium state of knowledge	Additional information has to be collected. Availability is not known; respectively difficulty to collect information is rising.
7/8	Low state of knowledge	Information is hard to find/achieve.
9/10	No knowledge	No information is currently available about that.

Table 4-1: First Draft of the Accessibility Rating Scale

For the feasibility, a similar scale was derived (see Table 4-2). At the beginning, it contained three slightly different descriptions. One for the feasibility itself, one for a comparison to existing products, and one for the overall probability of meeting the specification. The term 'candidate architecture' is used to describe the analyzed product architecture.

A low rating (1) indicates, that it is highly likely that the candidate architecture will meet the specification. This estimation is based on one's engineering knowledge or the fact that all similar products meet this specification. With an increasing rating, the feasibility becomes more and more challenging. For example, a medium rating (4/5/6) may be chosen because it is possible to meet the specification with the analyzed product architecture. This estimation may be based on the knowledge that products in distantly related fields meet this specification. A medium rating indicates that it is not impossible to meet the specification, but that is also not very easy to achieve this. The highest rating (9/10) is appropriate if nothing suggests that the specification will be met.

Rating	*Verbal description*	
1	Feasibility is very high	All similar products on the market are known to meet this specification.
		It is highly likely that the 'candidate architecture' will meet this specification.
2/3	Feasibility is likely	Other similar products in related fields are known to meet this specification.
		It is likely that the 'candidate architecture' will meet this specification.
4/5/6	Feasibility is moderate	Distantly comparable products are known to meet this specification.
		It is possible that the 'candidate architecture' will meet this specification.
7/8	Feasibility is challenging	Only one product on the market meets this specification (unique selling point, exclusive know-how).
		It is challenging that the 'candidate architecture' will meet this specification.
9/10	Feasibility is highly challenging or almost impossible	No product on the market that is known to meet this specification.
		It is very hard to impossible that the 'candidate architecture' will meet this specification.

Table 4-2: First Draft of the Feasibility Rating Scale

For the assessment of the severity of a risk, the decision was made to express the severity by the existence of alternative options. Not only the severity of consequences is estimated, but also alternatives that mitigate potential deficiencies. The question has to be answered, if there are other options in case the current product architecture does not meet the specification. An alternative is considered as anything that will achieve the specification, from a minor change (e.g. a change in material) up to the replacement of a whole subsystem. Thus, the severity is expressed by means of the reciprocal amount of adequate alternatives.

Since the severity is estimated by the opportunity for recovery, the assessment scale was named contingency rating (see Table 4-3). It contains five levels of detail and its distribution is similar to the feasibility scale. Three descriptions are offered: a description for the effectiveness of alternative solutions, a description of their performance and effort-cost-efficiency, as well as a description of the easiness of replacement.

A low rating (1) indicates that a variety of alternatives exist. Substitution is easy and the solutions are equal in performance. An example for such an alternative might be a different material, which achieves a similar performance. The higher the contingency rating is, the less attractive are alternative solutions. This implicates an increasing dependency on the candidate architecture. For the highest rating (9/10), no alternative exists and the specification can only be met with the analyzed product architecture. The levels in between offer the possibility to rate the effectiveness of the alternatives: A medium rating (4/5/6) may indicate that other solutions exists, but that they are less convenient or less effective than the analyzed architecture.

Rating	*Verbal description*	
1	Very high effectiveness of alternative solutions	Alternative solutions are equal in performance and have an equal ratio of development effort and cost efficiency.
		Substitution is easy.
2/3	High effectiveness of alternative solutions	Alternative solutions achieve sufficient performance and have an appropriate rate of development effort and cost efficiency.
		Application of alternatives is inconvenient.
4/5/6	Moderate effectiveness of alternative solutions.	Alternative solutions have a less acceptable ratio of development effort and cost efficiency but achieve sufficient performance.
		The 'candidate architecture' is preferable.
7/8	Minor effectiveness of alternative solutions	Alternative solutions are significantly more difficult to develop and/or less cost efficient, while not yielding an equally significant performance.
		The 'candidate architecture' is outstanding and therefore clearly preferable.
9/10	No effectiveness of alternative solutions.	The specification can only be met with this 'candidate architecture'.
		No alternative solutions exist.

Table 4-3: First Draft of the Contingency Rating Scale

The refined assessment categories and scales form the core part of the risk management tool. They have been continuously refined and improved during the pilot test and the field study. The scales were more and more simplified since this turned out to be less confusing. Later, a graphic presentation for the scales was chosen since this allows a more intuitive assessment. The 1…10 ratings were dispersed on an axis. Verbal descriptions were added without assigning them directly to a numeric value. This provides enough guidance while not restricting the assessment too much. Thus, it is possible to choose a rating that reflects the situation best. The graphic scales are presented in the next chapter when the final version of the method is described.

4.5 Refinement of the Procedure

The other requirements were also incorporated into the method. The previous sections (sections 4.2 and 4.3) described the focus of the risk management tool (*REQs 1, 3*) as well as the assessment phase (*REQs 13, 14*).

This section discusses the remaining requirements that influenced the development of the method. The second requirement ("The method consists of clear steps that can be easily followed.") was the basis for the phrasing of the method. By interviewing colleagues of the Lean Product Development Group at MIT, the pilot test, as well as the field study (cf. chapter 6), expressions and phrasings were constantly refined. It is hoped that the steps and key elements of the method are precisely described by the end of the field study (*REQs 2, 8, 10*).

In addition, steps that are necessary for the preparation of the analysis are described in section 5.2.1 (*REQ 6*). A template was developed to accommodate the analysis (*REQ 7*). It is presented in chapter 5. Additionally, a short description of the method by means of a handout (see Appendix, p. 116) guides the participants through the analysis.

One of the fundamental objectives of the development of the method was to provide design teams with a tool that proactively manages specification risks inherent in a product architecture (*REQs 11, 20, 24*). The overall objective of the develop method is to achieve these goals. It is hoped that this is proofed by means of the field study, which is presented in chapter 6.

By emphasizing the application within a cross-functional team (*REQ 5*) in the method's description, the method should enhance different views of the product architecture. Thus, the whole team benefits by understanding potential risk factors in a better manner. In order to experience the effectiveness of actions taken (*REQ 23*), the Risk Priority Number should be recalculated and compared to the previous ones. Additionally, this may indicate a final status, when a certain RPN is reached (*REQ 19*).

This section gave a brief overview about the incorporation of the requirements that have not been addressed in the previous section. The method itself will be described in detail in chapter 5.

4.6 Summary

This chapter gave an overview of the development of the risk management tool. The requirements, which have been derived from a literature review, were briefly summarized (section 4.1). Afterwards, potential focuses of the risk management method were described in section 4.2. The decision was reinforced to concentrate on performance issues. Another variant would be a focus on risks related to the process of product development. This approach will not be followed up since it would be too extensive.

Section 4.3 briefly presented development of the first draft of the risk management tool. The first draft was based on the modified FMEA, which was tested earlier with data of the supply chain field study. This version has been modified according to the requirements. The method itself was then refined by means of an iterative improvement process.

The derivation of the assessment categories and scales was described in section 4.4. It was the most profound change in the procedure of the FMEA. Three categories were introduced to assess the likelihood and the severity of a risk. The accessibility of information and the feasibility form a means to estimate the probability of occurrence. The severity, however, is estimated by a single category. It referred to as contingency and expressed by the opportunity for recovery.

The incorporation of the remaining requirements was briefly presented in section 4.5.

This chapter gives the reader an impression how the method was developed. Note that not every intermediate version of the method was presented but only the most profound changes. The final version is named “Specification Risk Analysis Method” since it seeks to identify and manage risks of a product architecture regarding not achieving its specifications. It will be presented in detail in the next chapter.

5 The Specification Risk Analysis Method

This chapter describes the final version of the Specification Risk Analysis Method. First, the situation where the method can be applied best is characterized. Additionally, its objectives are presented in section 5.1. The individual steps are described in detail in section 5.2. Finally, the effects that can be achieved by means of this analysis are discussed (section 5.2.10). A summary in form of a table rounds of the chapter in section 5.4.

5.1 Situation and Objectives

The method is designed for an application in an early stage of the product development process. In the phase of Embodiment Design, one or sometimes several product architectures are elaborated. These are sometimes also called preliminary layouts, e.g. by PAHL & BEITZ [2006] (cf. Figure 3-6). The method represents a means for a critical review, and seeks to identify potential risks inherited in a product architecture.

It is most qualified for the analysis of a single product architecture, but also allows an assessment of several ones. For a single architecture, the method allows a detailed analysis and seeks to assign corrective actions and responsibilities. For two architectures ore more, it would take too much time and would not be very efficient to assign corrective actions for each candidate. Nevertheless, the Specification Risk Analysis shows the challenges the individual candidates might face. It has to be noted that the analysis for more than one architecture does not result in the choice of a solution but may form an important input for the decision (see section 6.4).

Thus, the method might be more appropriate after one candidate architecture is chosen. In the following, the procedure for one candidate will be presented. Limitations and changes that have to be made to analyze more architectures are discussed at a later point (see section 6.2.1).

Within the Specification Risk Analysis, risk is exclusively treated in the context of not achieving product specifications. Thus, the objectives can be summarized as three statements:

- The method identifies, assesses, and ranks product specifications that are most challenging to achieve.
- The method avoids product deficiencies and provides a systematic approach to develop appropriate mitigation measures.
- The method prevents time and cost-consuming changes at a later point.

The structured procedure helps the team to systematically identify, assess and mitigate the risk that product specifications may not be achieved. Furthermore, the method helps to rank the specifications according to their exposure to risks and monitors their status. It identifies

specifications that might become critical for the product's success and suggests addressing those first. Thus, the method seeks to avoid product deficiencies because a specification cannot be met or is not followed up at all. As an overall goal, time and cost-consuming changes in a later phase should be prevented.

In the following, the method will be presented in detail, theoretical as well by means of a small practical example. A field study with a several teams of a product development class will be described in chapter 6 and seeks to prove the statements mentioned above.

5.2 Procedure of the Specification Risk Analysis

In this section, the Specification Risk Analysis is presented. First, a brief overview of the procedure is given (section 5.2.1). This may be sufficient if the reader intends to get a first idea of the method. In sections 5.2.2 to 5.2.10, the individual steps of the Specification Risk Analysis are then described in more detail.

5.2.1 Overview

In this section, the procedure of the Specification Risk Analysis is characterized. The method contains nine explicit steps and addresses primarily the four phases: Identification, Assessment & Priorization, Mitigation, and New Situation & Monitoring. The Initialization phase is indirectly addressed by recommended tasks for preparation. However, the trigger of the method's application cannot be provided. This is a decision that is either made by company regulations, the management, or the team itself. As previously mentioned for the FMEA, the Munich Method Model represents an appropriate framework for choosing and adapting the right method [BRAUN & LINDEMANN 2003].

In Figure 5-1, a brief overview of the method is given. The individual steps are now described in detail in the following sections.

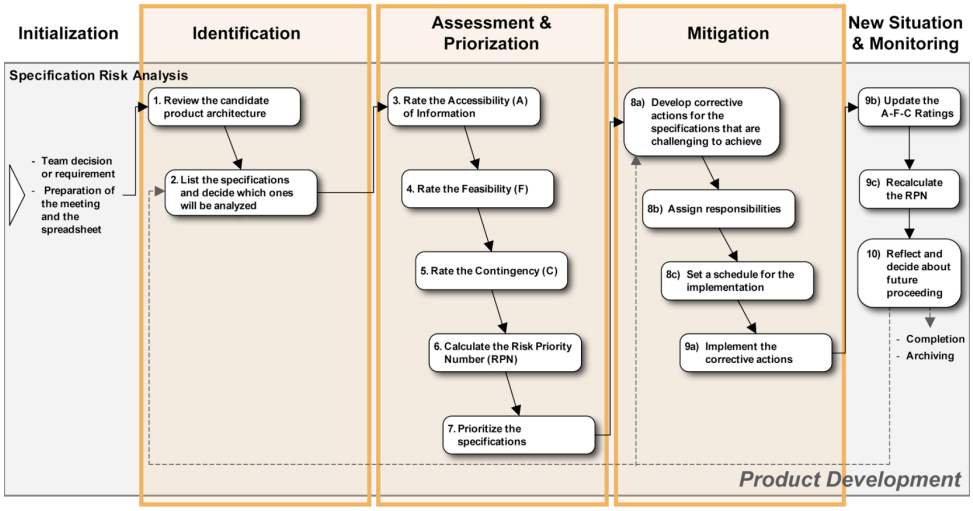


Figure 5-1: Procedure of the Specification Risk Analysis

After the decision is made to apply the method, the meeting has to be prepared. It is strongly recommended to choose a moderator who is familiar with the procedure. Furthermore, relevant members for the meeting have to be invited. It has to be ensured that designers who are particularly familiar with the product architecture will take part in the meeting. Furthermore, external members may broaden the perspective and bring up issues, which have not been noticed until then.

Before the analysis is conducted, it is useful to set up an agenda as a guiding timeframe. Appropriate handouts may be prepared, as well as a spreadsheet for the analysis, which contains all current specifications. Furthermore, any form of visualization for the candidate architecture is useful. Its presentation can range from simple drawings up to a computer-aided display of the conceptual architecture. The objective is to support discussions and make it easier for team members to specify concerns. The role of the moderator is to guide through the meeting, to help with upcoming questions regarding the procedure, and to reconcile in case of disagreements.

Then, the analysis can be started by reviewing the candidate product architecture. If changes have been made recently, it is reasonable that one team member briefly explains the current architecture to the others. This ensures, that everyone has the same understanding of it. Afterwards the product specifications are listed and reviewed. If the list is too long for a single meeting, the team may decide which specifications should be analyzed first. In the Identification phase not all possible risks of the analyzed product architecture or the product development process are regarded. For example, risks of customer acceptance or risk related to manufacturing are beyond the scope of the method. (An extensive overview of risks in general and in embodiment design in particular was given in sections 2.3.2 and 2.3.3) Only the ones are taken into account that concern the risk of not achieving product specifications.

In the Assessment & Priorization phase, each product specification is then analyzed regarding three key figures. First, it is estimated whether enough information has been collected to meet the product specification or how difficult it will be to collect additional information (step 3). Afterwards, the feasibility of achieving the specification is assessed, based on the engineering knowledge of the team. The third key figure is the product architecture's opportunity for recovery. In case this architecture does not meet the product specification, the contingency is estimated by means of the existence of alternative options (step 5).

After the key figures have been estimated, the Risk Priority Number (RPN) can be calculated by multiplying the ratings. The specifications can then be ranked by means of the RPN and the individual ratings. The risks are addressed afterwards in the Mitigation phase. It is emphasized that the team develops at least corrective actions for the most challenging specifications, indicated by a high ranking. Additionally, responsibilities for the tasks are assigned and completion dates are set.

After the corrective actions have been implemented, a new situation is achieved. The assessment of the key figures can then be reflected and repeated. The new, updated RPN rating helps the team to monitor the state of certain specifications and, if appropriate, triggers the development of further corrective actions.

5.2.2 Review of the Candidate Product Architecture

In the following, the individual steps of the method are described in detail. An example was derived from the field study and illustrates the procedure.

At the beginning of the method, the team reviews the product architecture that will be analyzed. The objective is to ensure that everyone has the same understanding. It may be useful if one participant briefly explains the structure and functions, and answers potential questions the team might have. The team members should familiarize themselves with the architecture. Different views should be discussed and open questions should be answered at this point.

A practical example will be presented in order to enhance the understanding. The exemplification was derived from an experiment of the field study with the Product Development and Design Class 2.739 at MIT. The team's objective was to develop "an easy to use, portable, user friendly, effective, stand alone tooth cleaning tool for travelers that is as comfortable as traditional in-home solutions" (see Appendix, p. 139). The exemplification should help the reader to get a clearer idea of the method after the theoretical description. The complete field study will then be presented and discussed in chapter 6.

5.2.3 List of Product Specifications

After having reviewed the product architecture, the product specifications are listed in the spreadsheet (see Figure 5-2). In addition, the assessments of the individual rating as well as short description will be described the spreadsheet. The spreadsheet covers the whole process of the method and forms a good mean to review the analysis.

If there is not enough time in the meeting to address all specifications, the team may choose the most important ones. However, the time for the meeting should not influence the number of specifications the team plans to address too much. If the team needs to address more specification, follow-up meetings should be scheduled.

A specification is derived from a customer need and usually consists of a verbal description, a value assigned and a unit. It has to be ensured that all specifications are up to date. Furthermore, it might be useful to prepare the spreadsheet prior to the meeting. Nevertheless, the list of specifications should still be reviewed in the meeting to check if there are any deficiencies.

The team of MIT's class 2.739 identified twelve specifications. Only one specification is described for the exemplification. It was derived from the customer need that the tooth cleaning tool should stay clean between the uses. Therefore, it has to comply with the specification "Presence of Harmful Bacteria". The unit "parts per million (ppm) over a specific time period" was assigned to it. This means in simple terms that the number of harmful bacteria on the toothbrush must not exceed a certain limit over a given period. At the point the analysis took place, the team had not defined a specific target value for this specification. Only the decision was made that their product to develop should be better than existing solutions.

No.	Specifications			Accessibility (verbal description)	Accessibility Rating (A)	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN	Re act
	Metric	Value	Unit								
1	Presence of Harmful Bacteria	*tbd* (better than existing solutions)	ppm over a certain time period								
2	Liquid / Gel Volume	<3	Oz								
3	Overall Size (if includes liquid/gel)	Fits 1qt Bag	Inches								
...											

Total RPN	0

RN	Recommended action(s)	Responsibility	Completion Date	Actions taken	Updated Accessibility Rating (A)	Updated Feasibility Rating (F)	Updated Contingency Rating (C)	Resulting RPN

Figure 5-2: Spreadsheet for the Specification Risk Analysis

5.2.4 Estimation of the Accessibility of Information

The following steps are repeated for each product specification. The first assessment estimates whether the current state of knowledge is sufficient to achieve the product specification or if additional information has to be collected. This dimension is named Accessibility (A). It is defined as *the uncertainty associated with getting the information needed to understand whether the candidate architecture will meet the product specification.*

Limiting conditions like the time frame or an existing budget have to be taken into account. The assessment can be easily estimated by answering the question ”Within the given constraints of time and money, how difficult is it for us to get the information needed to understand whether this concept will meet the product specification?” The estimation is then made by means of a 1…10 scale (see Figure 5-3). If the team feels certain that they have already collected enough information, the assessment would correspond to the lowest Accessibility rating (1). On the opposite site, the highest accessibility rating indicates that nothing suggests that the information needed can be found. The range in between gives the team the possibility to assess the difficulty to get the information. Similar to the FMEA, the rating represents more a means of comparison rather than an absolute value (cf. section 3.2.1, p. 32). Nevertheless, the team should agree on one number after a discussion.

Additionally, the assessment should contain a verbal description in the spreadsheet: The rationale is briefly described in the corresponding scale. This provides not only the documentation of the reasons behind the rating, but also emphasizes their traceability for later reviews.

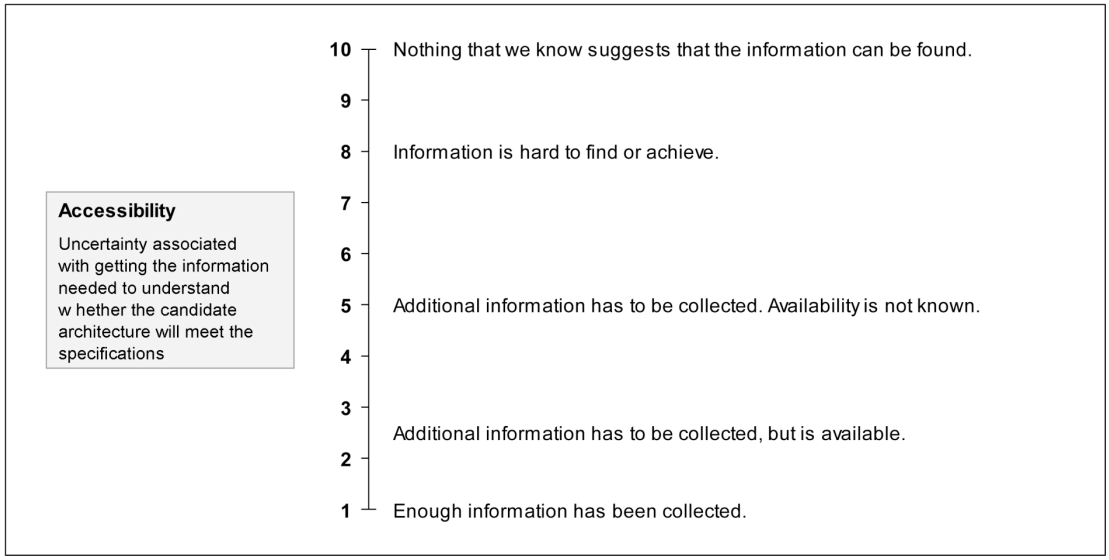


Figure 5-3: Assessment Scale for the Accessibility Rating

In the exemplification, the team of the class 2.739 decided that they did not know enough about the candidate architecture and its fulfillment of the specification "Presence of Harmful Bacteria". Thus, they needed to collect additional information. It was suggested to set up an experiment with the candidate architectures and concurrent products on the market. A swab should be taken from each of them and cultivated. After a specific time period, the number of harmful bacteria could be counted and compared. The team was very sure about the procedure of this experiment and had a good idea, how to get the information needed. However, they felt insecure about the remaining time period. When the analysis was conducted, three weeks were left to start building the final prototype. The team thought it would be very challenging to get additional information within the remaining time. Therefore, they chose an accessibility rating of 8 (see Figure 5-4).

No.	Specifications			Accessibility (verbal description)	Accessibility Rating (A)	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN	Re ac
	Metric	Value	Unit								
1	Presence of Harmful Bacteria	*tbd* (better than existing solutions)	ppm over a certain time period	We may set up an experiment (take a swab, compare it to existing solutions). It will certainly be challenging to get the information.	8						
2	Liquid / Gel Volume	<3	Oz	Enough information has been collected.	1						
3	Overall Size (if includes liquid/gel)	Fits 1qt Bag	Inches	Enough information has been collected.	1						
...											

Figure 5-4: Accessibility Rating for the Exemplification

5.2.5 Estimation of the Feasibility of the Product Architecture

By means of this rating, it is estimated if the product specification can be achieved. The Feasibility (F) is defined as *the likelihood that the candidate architecture will meet this product specification.*

The Feasibility Rating can be estimated by answering the question "Based on our engineering knowledge, how likely is it that we will meet the product specification with this candidate architecture?" The corresponding 1…10 scale (see Figure 5-5) is similar to the Technology Readiness Levels of the NASA (see [MANKINS 1995]). Though, it should only assess the feasibility of the analyzed architecture regarding the specification, not the overall technology. A low rating (1) indicates that the team feels certain about the achievement of the product specification. For example, this may be based on the fact that all similar products on the market are known to meet it. The higher the rating, the more challenging it will be to achieve the product specification. The highest rating (10) indicates that nothing suggests a potential achievement of the specification at the moment.

Again, the rationale for the assessment is described in the corresponding scale on the spreadsheet. This assists with the documentation and traceability of the team's decision.

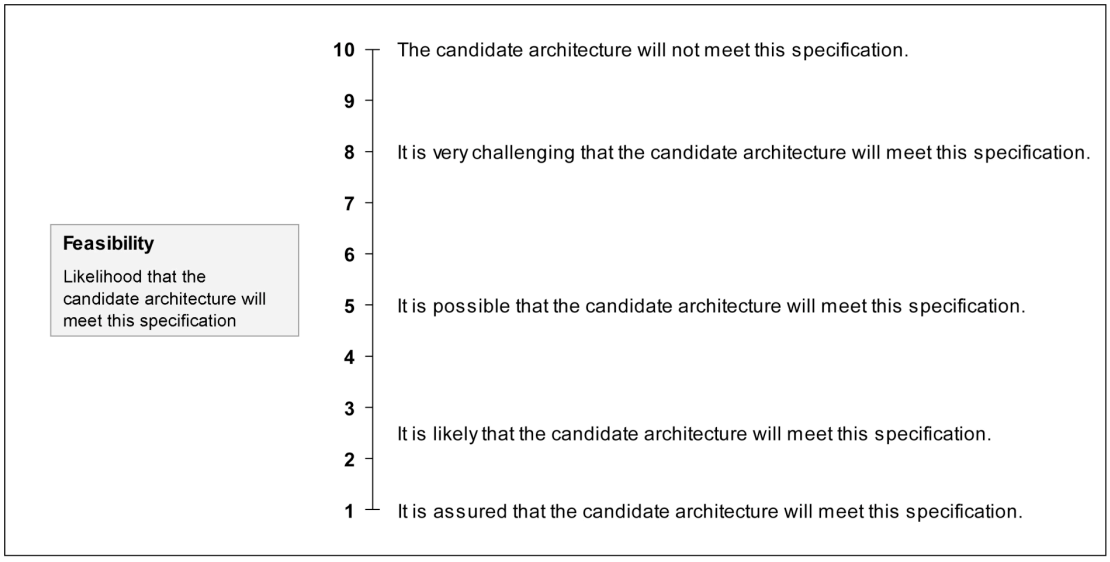


Figure 5-5: Assessment Scale for the Feasibility Rating

For the exemplification, the rating and the rationale for the feasibility are shown in Figure 5-6. The team discussed the characteristics of the candidate architecture briefly. Since it is very similar to existing solutions, they felt secure about the feasibility of the current architecture. Therefore, they came quickly to the decision to rate the feasibility with 2.

No.	Specifications			Accessibility (verbal description)	Accessibility Rating (A)	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN	Re ac
	Metric	Value	Unit								
1	Presence of Harmful Bacteria	*tbd* (better than existing solutions)	ppm over a certain time period	We may set up an experiment (take a swab, compare it to existing solutions). It will certainly be challenging to get the information.	8	We think it is likely to meet the specification because it's similar to exisitng solutions.	2				
2	Liquid / Gel Volume	<3	Oz	Enough information has been collected.	1	It is assured that this concept will meet the specification.	1				
3	Overall Size (if includes liquid/gel)	Fits 1qt Bag	Inches	Enough information has been collected.	1	It fits with other things in a bag.	1				
...											

Figure 5-6: Feasibility Rating for the Exemplification

5.2.6 Estimation of the Contingency of the Product Architecture

As the last rating, the contingency is estimated. It expresses the opportunity for recovery in case the architecture does not meet the specification. The Contingency (C) is defined as *the expression for the robustness of the candidate architecture, indicated by the existence of alternative solutions.*

The question “In case this architecture does not meet the product specification, do you know of alternatives?” helps to quantify the risk. An alternative is defined as any other variant that probably fulfills the regarded specification. It could be a simple change in material, dimensions, or even a completely different subsystem. For the assessment, the other specifications must not be neglected. It is important that the alternative solutions seem to be feasible regarding performance, development efforts and cost. At this point, however, a detailed assessment of all aspects is not possible. Thus, the fulfillment of all specifications can only be roughly taken into account.

Therefore, the scale for the Contingency rating offers a broad spectrum for the assessment (see Figure 5-7). A low rating (1) represents the existence of a variety of equivalent alternatives. Dimensions and especially materials sometimes offer a lot of options. With an increasing rating, the alternative solutions become less and less attractive. This may be appropriate if they influence the achievement of other objectives and specification in a negative manner. A high rating indicates that the team is not aware of alternatives, whereas the highest rating (10) has convinced the team that no alternative will achieve this specification. Additionally, it may be useful if existing alternatives are briefly described for a potential follow-up.

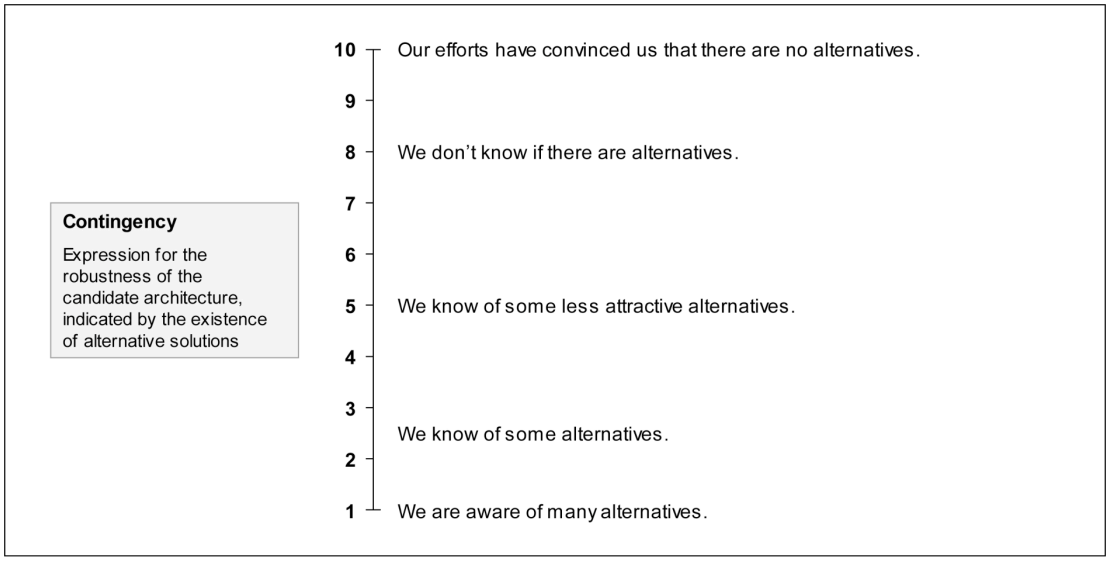


Figure 5-7: Assessment Scale for the Contingency Rating

Regarding the contingency, the team of the class 2.739 discussed several alternative options for their candidate architecture (see Figure 5-8). They came up with the idea to add mouthwash to the product or to use bacteria-killing toothpaste. Moreover, they could investigate the characteristics of available, antibacterial coatings or materials. Another alternative mentioned was to lower the recommended number of uses in order to minimize the bacterial growth on the product over time. However, all of the alternative options were less attractive than the existing one and therefore rated with 4.

No.	Specifications			Accessibility (verbal description)	Accessibility Rating (A)	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN	R… ac…
	Metric	Value	Unit								
1	Presence of Harmful Bacteria	*tbd* (better than existing solutions)	ppm over a certain time period	We may set up an experiment (take a swab, compare it to existing solutions). It will certainly be challenging to get the information.	8	We think it is likely to meet the specification because it's similar to exisitng solutions.	2	There are some alternatives (add mouthwash, antibacterical coating, bacteria-killing toothpaste, lower the recommended number of uses). Thus, they are less attractive.	4		
2	Liquid / Gel Volume	<3	Oz	Enough information has been collected.	1	It is assured that this concept will meet the specification.	1	We would simply change the size of the toothpaste box (dimensions).	1		

Figure 5-8: Contingency Rating for the Exemplification

The steps presented in the sections 5.2.4, 5.2.5, and 5.2.6 are repeated for every specification. For a long list, the analysis can become extensive, so that the team might consider analyzing only the most important ones. A single team member can then prepare the rest of the assessment and discuss it with the group in a future meeting. With the teams in the class 2.739 the assessments lasted about 30 to 45 minutes. Between 6 and 9 specifications were analyzed per team.

5.2.7 Priorization of the Specifications

After having assessed the Accessibility (A), the Feasibility (F) and the Contingency (C) during the last steps, the Risk Priority Number (RPN) can be calculated. This is simply achieved by multiplying the individual ratings (see Table 5-1). The Total RPN can then be calculated by adding up the RPNs of all specifications. If a digital spreadsheet is used as a tool for the analysis, the RPN and the Total RPN can be calculated simultaneously.

Risk Priority Number	=	*Accessibility Rating*	x	*Feasibility Rating*	x	*Contingency Rating*
RPN		***A***		***F***		***C***

Table 5-1: Calculation of the Risk Priority Number

A team should not be afraid of high Risk Priority Numbers. The RPN ranges from 1 to 1000, and other teams would probably come to different results for the same candidate architecture. The RPN is a means to compare the single product specifications to each other rather than an "absolute" value. This was also discussed for the FMEA in section 3.2.1 (see p. 32).

For the exemplification from the experiment with the class 2.739, the resulting Risk Priority Numbers (RPN) are shown in Figure 5-9. For the previously assessed product specification, the calculated RPN is 64, derived from the multiplication of the individual ratings.

No.	Specifications			Accessibility (verbal description)	Accessibility Rating (A)	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN
	Metric	Value	Unit							
1	Presence of Harmful Bacteria	*tbd* (better than existing solutions)	ppm over a certain time period	We may set up an experiment (take a swab, compare it to existing solutions). It will certainly be challenging to get the information.	8	We think it is likely to meet the specification because it's similar to exisitng solutions.	2	There are some alternatives (add mouthwash, antibacterical coating, bacteria-killing toothpaste, lower the recommended number of uses). Thus, they are less attractive.	4	***64***
2	Liquid / Gel Volume	<3	Oz	Enough information has been collected.	1	It is assured that this concept will meet the specification.	1	We would simply change the size of the toothpaste box (dimensions).	1	***1***
3	Overall Size (if includes liquid/gel)	Fits 1qt Bag	Inches	Enough information has been collected.	1	It fits with other things in a bag.	1	There are a couple of alternatives: take the toothbrush out of the bag, change the design (shape), change the repository of the toothpaste	2	***2***
...										
									Total RPN	67

Figure 5-9: Risk Priority Numbers for the Exemplification

By means of the Risk Priority Number, the product specifications can then be prioritized according to their exposure to risk. This helps the team to identify potential deficiencies of the product architecture they haven't realized so far. The team has to decide which specifications they would like to address first. There is no critical RPN recommended, as this has to be determined individually for each analysis. Nevertheless, it may help to set a threshold.

A Pareto diagram may also be useful to visualize the ratings. It helps to get a better understanding about the accumulated share of the risks in the Total RPN. In the example presented below (see Figure 5-10), the three highest ranked risks make up more than 90 % of the Total RPN. The diagram suggests to address at least those three specifications in order to minimize the risk of not meeting the specifications.

However, no universal recipe can be given which specifications should be addressed. The priorization and the Pareto diagram only suggest where to start. The ranking of the specifications gives the team a good idea which ones might be challenging to achieve. It does not indicate that the team is not able to achieve those specifications but that it might be harder - compared to others. The highest ranked specification can be interpreted as exclusion criteria for the final product. The sooner it is known if the product will meet those specifications the lower the overall risk is.

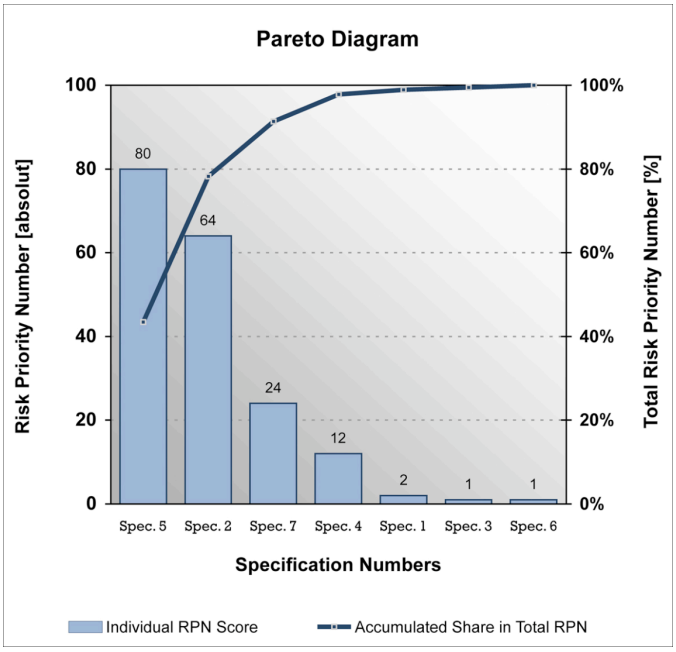


Figure 5-10: Example for a Pareto Diagram

But the highest ranked risks are not the only ones that should be addressed. Additionally, it is important that product specifications with high individual ratings are also considered. The decision which specifications will be addressed has to be made by the team and depends on their risk-attitude, the analyzed product architecture and the overall situation. For example, the importance of the product within a company's portfolio may play a role. If the development of a product is a pilot project and the company is not highly dependent on its success, the team may be willing to take more risks.

As already mentioned in section 3.2.1, a sensitivity analysis may be highly beneficial. The assigned numerical values and the calculated RPN might infer objectivity. However, they represent subjective assessments of the situation. Thus, a sensitivity analysis may help to achieve more insights about certain risks and their assessments.

5.2.8 Development of Corrective Actions

As discussed earlier, a challenge implies that there are responsibilities, efforts, and options. The situation can be controlled and managed (see section 2.3.1). After the team has decided which specification they plan to address in the previous step, corrective actions have to be developed. The most severe risks – indicated by a high RPN rating or a high individual rating – should be addressed first. However, actions can also be recommended for other risks even if they have a lower RPN rating, e.g. if a specification risk can be minimized with little effort. The corrective actions are described in the spreadsheet and a responsible person as well as a completion date is assigned. The recommended activities may address one or more of the following aspects:

- Achievement of additional information (e.g. literature review, tests, surveys, ...)
- A reviewed estimation of the feasibility (e.g. due to calculations, simulations, …)
- Development or improvement of alternative solutions

The achievement of additional information addresses the Accessibility Rating (A). If the information needed can be collected or at least a source identified, the new, updated rating will be lower than the initial one. The team may consider surveys, tests, a literature review, or simply an Internet research to get additional data. For all product specifications with an Accessibility Rating of 2 and higher, a responsible person should be assigned to get the information needed.

A review of the feasibility of the candidate architecture addresses the Feasibility Rating (F). Therefore, calculations, simulations or research about similar products may be conducted. Anything, which helps the team to re-estimate the feasibility, is useful if it is proportionate to its efforts.

The development or improvement of alternative solutions lowers the Contingency rating (C). The actions may range from simple ones, like the evaluation of other appropriate materials, up to very complex tasks. An example therefore is the development of a completely new subsystem of the candidate architecture.

In the exemplification, the team of the project “Combination of Toothbrush and Toothpaste” considered two actions (see Figure 5-11). As mentioned before in the Accessibility Rating (see section 5.2.4), they were concerned if it is possible to get additional information within the remaining three weeks. One member of the group had access to a lab, where swabs taken from the product to develop and existing solutions can be cultivated. However, the team still felt insecure if an experiment could be set up on time. Thus, the team decided to investigate the feasibility of the experiment first. By means of an experiment the presence of harmful bacteria can be identified and compared.

As a second action, they decided to gather additional information. The team already thought that the achievement of the specification “Presence of Harmful Bacteria” was pretty feasible and assigned a rating of 2. If this assumption can be verified, the new updated rating may be even 1. Therefore, the team decided to get additional data about existing products by means of an Internet research. If similar, existing solutions don’t have any problems with bacteria, it

can be assumed that the product to develop will not have any either. However, the team had plenty ideas what they could change in case the candidate architecture does not meet the specification (see the Contingency Rating, section 5.2.6).

Since not every team member took part in the meeting, the assignment of a responsible person and a completion date was scheduled for the next team meeting.

No.	Specifications				RPN	Recommended action(s)	Responsibility	Completion Date	Actions taken
	Metric	Value	Unit						
1	Presence of Harmful Bacteria	*tbd* (better than existing solutions)	ppm over a certain time period		***64***	Check if we can set up experiments Check if there is information online (existing solutions) so that we can assess the feasibility	Will be discussed in one of the next team meetings.	Will be discussed in one of the next team meetings.	
2	Liquid / Gel Volume	<3	Oz		***1***				
3	Overall Size (if includes liquid/gel)	Fits 1qt Bag	Inches		***2***				
...									

Total RPN	67

Figure 5-11: Corrective Actions for the Exemplification

5.2.9 Implementation of the Actions and Monitoring

As a last step, the corrective actions previously developed are implemented and the specification risks are monitored. The monitoring of the risks is achieved by re-estimating the individual assessments. After the recommended actions have been implemented, a new, resulting RPN can be calculated. The "Resulting RPN" should be significantly lower than the previous one – otherwise the actions have not been effective. The reduction of the Total RPN is a further indicator. The results can also be shown in the previous Pareto diagram to visualize the effects of the actions.

5.2.10 Reflection and Decision about Future Procedure

After the product architecture has been analyzed regarding its specifications risks and corrective actions have been implemented, the RPNs are updated. This does not only monitor the current risks but also necessitates a decision about the future proceeding.

Lean Product Development seeks to constantly improve all parts of a system and involves all relevant parties (paradigm of perfection). Thus, it is advisable to review the procedure and results of the Specification Risk Analysis. Potential improvements for further applications may be gained.

At this point, the team has two options: First, if the team is content with the effects of the mitigation measures and the achieve options, it can finalize the method and archive its results. This is advisable due to reasons of documentation and as a help for future projects. Second, if the team is not content with the results, they may go on with step 6. Since there is no target RPN that has to be achieved, there may be several iterations. It is the decision of the team or the management how much risk they are willing to accept. It is not deemed necessary, that the analysis is always conducted in a team. For a follow-up, it may be possible, that one team member updates and reviews the ratings and present his results to the group. Thus, controversial decisions can still be discussed without taking too much time.

5.3 Effects of the Analysis

By means of the analysis, several effects can be achieved. First of all, the method represents a structured approach for the team to review their current product architecture. It ensures that no specification falls behind – not matter if that had happened unintentionally or intentionally. The method avoids assigning blame to anyone, and it allows every team member to express his or her concerns. However, this is not achieved exclusively because of the method and is also influenced by aspects of project management, leadership etc. But a structured, objective approach emphasizes the expression of concerns that might have been concealed otherwise. This also described in a similar way in [PDMA 2002, Firebird Project, p. 189] where a risk management approach helps a team to express its concerns about a project without embarrassing the enthusiastic team leader.

Furthermore, the method presents an approach to document product specifications that might become difficult to achieve. Corrective actions, responsibilities, and implementation dates are written down as well. This helps to follow up the critical specifications identified. Additionally, the documentation of challenging specifications and developed actions may give teams with similar projects a good idea what challenges they might face and how to address them.

5.4 Summary

A detailed description for the Specification Risk Analysis Method was presented in this chapter. A shorter version can be found in the materials of the field study (see Appendix, p. 116).

A short and concise overview of the method is given in Figure 5-12. Its structure is derived from LINDEMANN [2006A, p. 239 ff.] who presents an extensive collection of methods in product development.

The figure briefly describes the objective and effects of the method, as well as the procedure and the situation in which it is applied. Furthermore, appropriate tools are recommended and some general comments are provided. The overview facilitates a quick understanding and briefly presents the key elements of the Specification Risk Analysis.

SPECIFICATION RISK ANALYSIS

Objective	*Situation*	*Effects*
• Assessment and ranking of which product specifications are most challenging to achieve • Avoidance of product deficiencies • Prevention of time and cost-consuming changes in a later phase	• In an early stage of the product development process, when one or more product architectures have been elaborated. • Critical review of the potential candidate architecture(s) • In the context of analyzing properties and ensuring the achievement of goals	• Documentation of product specifications that might become difficult to achieve • List of corrective actions, assigned responsibilities and completion dates • Documentation of know-how

Procedure

- Review the conceptual architecture
- List the product specifications of the analyzed object
- For each product specification, describe and estimate:
  - The accessibility of the information needed to achieve the product specification
  - The feasibility of achieving the specification based on the engineering knowledge
  - The contingency – opportunity for recovery – in case this architecture does not meet the product specification
- Calculate the Risk Priority Number (RPN) by multiplying the three ratings
- Assess the current state of the architecture by means of the RPN ranking and the individual ratings
- Develop corrective actions, assign responsibilities, and set a schedule
- Repeat the assessment after the implementation of the actions
- Decide about future proceeding

Tools

- Any form to visualize the conceptual architecture may be useful.
- Form based on a spreadsheet

Notes

- The assessment of the RPN needs to regard the individual factors, which it consists of.
- The method does not regard all possible risks to the analyzed product architecture or the product development process. Only the ones that concern the risk of not achieving product specifications are considered.

Figure 5-12: Description of the Specification Risk Analysis

6 Field Study

In the following, a field study is presented that was conducted with a product development course at MIT. It discusses the application of the Specification Risk Analysis described in chapter 5. At the beginning, the conduction of the study is described in section 6.1. The gained data is analyzed in section 6.2. Afterwards, the feedback of the participants is presented (section 6.3). A generic conclusion about the field study and the method itself is drawn at the end of this chapter (section 6.4).

6.1 Conducting the Field Study

First, the objectives of the field study are briefly described (section 6.1.1). Then, the setting of the study and the individual teams are described in section 6.1.2. Its methodology is presented afterwards (section 6.1.3). Finally, the execution of the field study is described in section 6.1.4.

6.1.1 Objectives

Testing and Refinement of the Specification Risk Analysis

The field study seeks to achieve two objectives. First, a practical application of the method should be obtained. Current deficiencies of the procedure as well as potential improvement should be identified. It is hoped to gain experiences with the application, as well as feedback and recommendations from the participants.

The gained insights should then be used to revise and continuously improve the procedure of the Specification Risk Analysis. Additionally, the field study should indicate the optimal time in the prod11uct development process for its application. Finally, it should be proven, that the method helps designers to minimize the risks of not achieving specifications and that significant benefits can be achieved.

Assistance for the Development Teams Regarding their Key Challenges

One of the fundamental objectives of the method is to help development teams to identify and manage key challenges regarding product architectures. Thus, the second objective of the field study is to assist the teams of the course 2.739 within their projects.

Since participating in the study was optional for the teams, they needed to be convinced that they would achieve valuable benefits. Thus, the second objective of the field study was to offer a structured approach to the participating teams to review their candidate architectures. Key challenges and potential risks they might face should be identified. The analysis should help the teams to identify uncertainties associated with their architectural choice. Since their timetable was very strict, the teams needed to concentrate on key aspects.

Therefore, the teams should benefit from the method by assessing and prioritizing their most important specifications, and revealing potential product deficiencies. Furthermore, first ideas for corrective actions should be elaborated in the meetings.

6.1.2 Setting

The field study was conducted with four teams of MIT's course 2.739 in the Spring Term 2007. It is a class that is attended by MIT students and Industrial Design students from the Rhode Island School of Design (RISD) in Providence, RH. The class is named "Product Design and Development" and covers tools and methods for product design and development.

The course is built around a team project where small groups (6-7 students) develop a product together. The students come from different fields of management, engineering, and industrial design. Most of them are graduate students (M. Sc. or Ph.D.), with a few exceptions of senior undergraduate students. The teams conceive, design, and prototype a physical prototype of their product within 14 weeks.

The field study was conducted between the 9th and 11th week of class, at the beginning of April. The syllabus of the class expected the teams to present a final concept including a model and renderings within the 10th week. Furthermore, many of the groups planned to prototype their products during Spring Break in the last two weeks of March. Thus, it was reasonable to assume that the teams would have a concrete idea of their product architecture in mind.

The participation in the field study was optional for the teams. Four teams decided to take part, which will be briefly presented in Table 6-1. In the first row, the teams are listed. Then, a short description about their objectives is given (named "Mission Statement" within the course). The team size is listed in the third row. All teams included one industrial designer and at least one engineer.

After the teams had started to define their product architectures, a meeting with each group was held and the risk analysis was conducted. The meetings took place beside the regular course work of the class and lasted about an hour. The date of the meeting within the field study is given, as well as the number of participants. Contrary to the prior assumption, not all teams had narrowed down their candidate architectures to a single choice. Thus, the last column contains the number of analyzed architectures for each team.

The first team is named "Chalkboard Eraser" (see Table 6-1). Its objective was to improve the type of chalkboard eraser that is currently used in most US-American schools. The meeting with three out of the six team members took part in the 9th week of class (Apr 3rd 2007). At this point, the team considered three candidate architectures.

The second team ("Drinks and Hors d'Oeuvre without a Table") sought to develop a product that will allow the user to hold both a plate and a cup in one hand while attending stand-up reception. All seven students attended the meeting for the risk analysis later in the 9th week of class. They analyzed their four remaining candidates.

The team "Combination of Toothbrush and Toothpaste" had already chosen one product architecture. The analysis took place a week later (10th week of class, Apr 10th 2007) and the group had already proceeded farther down the development process. Three students out of six could participate in the meeting.

The objective of the last team in the field study, the team "Adjustable Insulation Jacket", was to develop a jacket for outdoor activities whose insulation level can be adjusted according to the situation. Unfortunately, only two of six members could attend the meeting in the 11th week of the course (Apr 18th 2007).

Team	Chalkboard Eraser	Drinks and Hors D'Oeuvre without a Table	Combination of Toothbrush and Toothpaste	Adjustable Insulation Jacket
Mission Statement	Development of a chalkboard eraser that minimizes dust while removing chalk marks of all colors quickly and affordably.	Development of a product that will allow user to hold both a plate and cup/glass in one hand easily and safely.	Development of an easy to use, portable, user friendly, effective, stand alone tooth cleaning tool for travelers that is as comfortable as traditional in-home solutions.	Development of an easy to use, durable, comfortable jacket with adjustable insulation levels for the outdoor environment.
Team Members	6	7	7	7
Date of Experiment (class week)	Apr 3rd 2007 (9th week)	Apr 5th 2007 (9th week)	Apr 10th 2007 (10th week)	Apr 18th 2007 (11th week)
Participants	3	7	3	2
Analyzed Architectures	3	4	1	1

Table 6-1: Overview of the Participating Teams in the Field Study

By means of this section the reader should receive a first impression about the participating teams in the field study. More detail about the analyses will be given in section 6.2 and in the Appendix (p. 122 ff.). In the following, the methodology for the field study will be described.

6.1.3 Methodology

Pilot Test

Before the method was applied in the field study, a first draft was executed in a pilot test in early March. It was conducted in the weekly meeting of the Lean Product Development group of MIT's Engineering Systems Division. Since the group has not been developing a product, a practical example was derived from MIT's class 2.009. This course takes place in the fall term and is referred to as "Product Engineering Processes" class. Within 14 weeks, senior undergraduate students work in large teams to design and build working alpha prototypes of a product [MIT COURSE 2.009 HOMEPAGE 2006].

One project of this class was chosen as an example for the pilot test. The product was easy to understand, and enough information was available on the course homepage. Its purpose was to develop an attachment for existing treadmills in order to make running safer and more comfortable for blind runners. The specifications, which were derived by the students' team, as well as some of their concepts, were prepared to form a starting point for the pilot test.

The Lean Product Development group was then asked to split up into two teams, to pick one

of the provided concepts, and develop it into a product architecture. By means of this task, the group got familiar with the specifications and the product itself. After forty minutes the teams were asked to rejoin and to conduct the analysis of one product architecture together.

By carefully observing the pilot test and through the group's feedback, some insights could be derived regarding improvements for the procedure. The method was then revised before the next tests were started.

Iterative Revision and Continuous Improvement in the Field Study

In order to prepare the meetings with the teams of course 2.739 the engineers were asked for the team's current list of specifications as well as the latest drawings, sketches, or pictures of their architectures. Then, the spreadsheets and handouts for the analysis could be prepared. An example for the handouts is presented in the Appendix (p. 115 ff.).

The author was the moderator of these meetings and guided through the procedure. Due to the time constraints, not all specifications could be analyzed. Thus, the most important ones for the customer were chosen. When the teams identified the customer needs of their product, they also had to assign an importance rating on a 1…5 scale. Those ratings were chosen to be an indicator to identify the specifications that will be analyzed.

The field study was conducted according to the steps described in the handout. During the assessment, notes were taken by means of spreadsheets. Additionally, the meetings were recorded and thus, the spreadsheets could be completed afterwards. It was then sent back to the team with further recommendations how to proceed.

Observing the application and conducting surveys within the participants identified the effectiveness of the method and further room for improvement. Those insights were integrated in the procedure before the meeting with the next group took place. Thus, a continuous improvement of the method could be achieved.

6.1.4 Execution of the Field Study

The field study was executed in the first weeks of April 2007 (see section 6.1.2). One of the first difficulties was to contact the teams and start communicating with them. The teams were not forced to assign a leader or project manger. Therefore, most of them did not have a structure or hierarchy. Because only one team responded to a generic offer in class, on the course homepage, and reminders per email, the other groups were contacted by establishing communications with the engineer in the groups. Thus, three more groups could be convinced to participate in the study.

Since the students' time besides classes and homework is marginal, and most of the team members have different schedules, it was quite difficult to arrange meetings with them. Therefore, the meetings were mostly scheduled on the short term. Additionally, it was promised that the meeting would last about an hour. Because of this time constraint not all specifications could be analyzed in the meetings.

The experiments with the first two teams took place while they were still considering several concepts. This first team developed an improved product to replace existing chalkboard

erasers (see Table 6-1 and Appendix, p. 124). At this point, the team considered three very different architectures. However, none of them was elaborated in much detail and the requirements were still broadly defined.

The second team developed a plate that should accommodate food and drinks at semi-formal drinks and hors d'oeuvres receptions (see Table 6-1 and Appendix, p. 132). The whole team attended the risk analysis and four potential concepts, which they still considered, were discussed. The candidate architectures have been specified on a medium level of detail, but the team had a concrete idea of the individual architectures in mind. Additionally, they had done a lot of prototyping in advance and described their specifications in detail.

When the analysis was conducted with the last two teams, they had proceeded farther down the process. The third group had already narrowed down their selection to a single product architecture. Their mission was to combine toothbrush and toothpaste in one tooth cleaning tool (see Table 6-1 and Appendix, p. 139).

In the 11th week of the course syllabus, the last experiment took place (see Table 6-1 and Appendix, p. 143). Two engineers of the team "Adjustable Insulation Jacket" analyzed the chosen candidate architecture regarding its key challenges.

6.2 Analysis

This section discusses and analyzes the data gained through the field study. In section 6.2.1, the results regarding the point of application in the product development process are presented. The field study revealed several improvements for the method's procedure, which are described in section 6.2.2. Finally, the results of the method are discussed (section 6.2.3).

6.2.1 Results regarding the Point of Application

The field study identified two potential applications for the method in the product development process: First, in order to compare several candidate architectures; and second, for a single product architecture in order to identify and manage challenging specifications.

For the first two teams, several architectures were analyzed. While for the first team the architectures were analyzed in a sequence (Team "Chalkboard Eraser", p 124), the variants of the second team were analyzed at once (Team "Drinks and Hors d'Oeuvre without a Table", p. 132).

It seems that it is much more efficient to analyze the architectures in parallel. The example in Figure 6-1 shows a parallel assessment for four candidates. It was derived from the field study. The variants address the same specifications since they had been elaborated from one concept. Thus, it is easier to compare the architectures to each other. For a deeper analysis of the individual architectures, is it useful to separate the ratings afterwards and examine each variant in detail.

No.	Requirements Specifications	Concepts	Accessibility (verbal description)	Accessi-bility Rating (A)	Feasibility (verbal description)	Feasibi-lity Rating (F)	Contingency (verbal description)	Conting-ency Rating (C)	RPN
1	Weight unit supports	J	Much information has been collected form existing products, however additional information needs to be collected.	2		3	The structure of this concept can be compounded, another material chosen...	2	**12**
		I		2		3	see Concept J	2	**12**
		M		2	Due to the length of this concept it is more challenging to achieve this specification (momentum arm).	5	Due to its dimensions, it's slightly more challenging to strenghten the structure of this conecept (make it shorter, different structure). The alternatives would be less attractive.	3	**30**
		A		2		3	see Concept J	2	**12**
2	% of food unit can accommodate	J							**0**
		I							**0**

Figure 6-1: Assessment of Several Product Architectures

On the negative side, the method is not formed as a structured approach to select the best candidate architecture. It does not explicitly support the decision making process. Nevertheless, the results gained by the Specification Risk Analysis may be an important input for this decision. However - before the choice has not been narrowed down to one concept - developing mitigation measures for the individual risks does not make sense and results in too much work. The only corrective action, which was assigned in those meetings, was collecting additional information regarding certain specifications. The intent was to get enough data to achieve an objective decision and to make sure that the highest ranked specifications can be fulfilled.

When the field study was conducted with the third and fourth team, they had already narrowed down their choice to one product architecture (Team “Combination of Toothbrush and Toothpaste”, p. 139; Team “Adjustable Insulation Jacket”, p. 143). Thus, it was possible to complete the method and to discuss corrective actions. Since their product architectures were elaborated in more detail, the analysis was more accurate and could concentrate on specific issues of the design.

In summary, both applications seem to be useful. However, for the assessment of several architectures the Specifications Risk Analysis represents more a quick, structured review than a risk management tool. By means of this review, it can be estimated whether some specifications might become extremely challenging to achieve or cannot be met. Additionally, the Total Risk Priority Number sets the candidates in proportion to each other. The teams, which compared three respectively four variants, chose the “less risky” solution for their further procedure. For both of them, one architecture inherited significantly lower risks than the other ones. Although the other variants might have included other advantages, the objectives could be achieved with a lower risk of performance deviations. Additionally, it has to be taken into account that this decision was enforced due to the time pressure the groups faced.

6.2.2 Improvements regarding the Procedure

As mentioned earlier, the procedure of the method was continuously refined during the field study. Whereas the basic procedure was clear from the beginning on, room for improvement could be identified. Thus, an ongoing refinement enhanced the method. The following insights could be achieved:

- If various architectures were analyzed, they were analyzed in parallel. Thus, the candidate architectures can be better compared and it takes less time than a sequential analysis.
- Requirements can be interpreted too broadly. Specifications are more accurate and provide less room for interpretation. It was found to be useful if target values (or at least an interval) were already defined.
- The description of the procedure was simplified until an appropriate level of information was achieved.
- The number of participants does not necessarily correlate with the quality of the results. Nevertheless, at least three participants from different fields were found to be reasonable.
- An experienced moderator considerably contributes to a successful meeting.

The analysis of various architectures was already described in detail in the previous section. A parallel analysis is less time consuming and enables an easy comparison between the individual variants. It was considerably better than a sequential analysis.

The first group in the field study had not explicitly derived specifications from their list of requirements. In the meeting, discussions were manifold because it was not clear if the architecture would fulfill a certain requirement. The reason was the different interpretation of a requirement by the team members. Therefore, as it was already anticipated in section 4.4, the term ‘requirement’ was narrowed down to ‘specification’. Especially regarding the feasibility rating, specifications provided less room for interpretation. It was found to be useful if the team had assigned target values, or at least a target range. Then, discussions were based on existing facts rather than assumptions.

Regarding the reduction of information, the procedure was improved iteratively. The basic procedure included the approach of the FMEA as well as the three assessment dimensions presented earlier: Accessibility, Feasibility, and Contingency. For the first teams, the description of the Specification Risk Analysis was rather scientific. This was perceived to be confusing and contained too much information. More information does not necessarily improve the method. This was also shown in a study by GRAEBSCH [2005], who identified over-information as a non-value adding activity in Lean Product Development. However, it was not clear at the beginning which level of information was appropriate. The procedure was simplified from meeting to meeting and unnecessary information was eliminated. It was easier for the teams to follow a highly simple description, which did not explicitly include any definitions. The three dimensions of the assessment were still addressed, but through another

approach: The Accessibility, Feasibility, and Contingency were implicitly estimated by means of simple questions. The description of the approach, which turned out to be most appropriate, is shown in the Appendix (p. 116). Nevertheless, the definitions of the assessment categories are still provided on the side of the scales.

Another aspect identified in the field study was, that the size of the team does not correlate much with the results of the analysis. Due to different schedules, universities, etc., it was very difficult for the project teams to find a time to meet with all members. Thus, only some team members conducted the risk analysis, and presented the results to their peers afterwards. Only one team participated with all seven team members. For the other teams, the number of participants ranged from two to four. No explicit disadvantage could be identified if not all members can conduct the analysis. The meetings, in which all members took part, ensured that everyone in the team had the same understanding of the current product architecture. Additionally, every team member could express his or her concerns and thus, a deeper insight could be gained.

Nevertheless, the meetings, in which not every team member participated, did not seem to be less successful. Only for the team with two participants, a third or forth member would have been useful. Both participants were engineers and thus, a very technical or rational consideration took place. In the other meetings, team members from other fields usually provided additional insights and often addressed aspects overseen by the engineers. The discussions in the cross-functional teams were manifold and showed lots of different aspects, especially in the discussion of corrective actions. In the meeting with the two engineers, they agreed mostly about concerns and issues. In general, the team size did not correlate with certain results. But an analysis with at least three participants with a different background seems to be reasonable.

The execution of the method was improved from meeting to meeting. The first reason was that the procedure was refined continuously as described above. The second reason was that the author got more and more experienced as a moderator in the meetings. Thus, more guidance could be provided. The experience gained in the previous meetings turned out to be helpful in the following ones. For future applications, it is advisable to have an experienced and well-trained moderator who guides through the analysis. Additionally, the team has to be aware of the fact that they have to get to know the method and its procedure.

In summary, details of the method were refined whereas the fundamental approach from the beginning turned out to be thoughtful and reasonable. The insights gained by the field study were very useful. In order to review the results, which can be achieved by the method, the next section discusses its outcomes.

6.2.3 Results regarding the Outcomes of the Method

The obvious outcomes of the methods are a prioritized list of specifications, assigned corrective actions, responsibilities, and due dates. But also other, more implicit and hidden outcomes can be achieved.

First of all, the method is a good possibility to review their current architecture together as a team. Different opinions can then be discussed and open issues can be identified. Within the field study, it was often observed that team members disagreed on certain aspects of the architecture or were confused by the explanation of their peers. Comments like *"I thought, we would do it (...) this or that way."* or *"Haven't we recently decided, that this wouldn't be an option anymore for us?"* were often recognized in the meetings.

By means of the structured approach, the method provides a mean to review the candidate architecture systematically. Not only the architecture is reviewed regarding specification risks, but open issues, which have not been obvious for some members, can be identified, discussed, and clarified. Thus, the method helps to align the team's mental models of the architecture.

A second advantage can be achieved by this systematic review. By carefully analyzing each of the specifications, aspects that have fallen behind can be identified. Some of the teams were surprised that they hadn't followed up all specifications. For example, two specifications of the team "Combination of Toothbrush and Toothpaste" achieved a risk priority number 30 times higher than the other specifications. This was visualized very impressive by means of the Pareto diagram (see Appendix, p. 141).

Additionally, the method reveals if all specifications are up-to-date. During the individual team meetings, some specifications were eliminated because they had become obsolete. Other specifications were modified or described more precisely. Some teams refined their specifications, or thought about splitting a specification into several ones. Sometimes even new specifications were introduced because the team realized that some objectives were not covered by their current list.

Furthermore, the method assisted the teams regarding their future procedure. Even if the method is not designed as a decision making tool, the insights and results gained by the analysis may help as the product development process continues. Both teams that analyzed various architectures chose to proceed with the one that achieved the lowest overall risk score. For the analysis, they used the – from their point of view – most promising candidate as a basis and compared the other variants to their favorite one. Aspects could be identified which were solved particularly well by other variants, and shortcomings of the favorite architecture could be identified. To one team's surprise, their favorite architecture was not necessarily the one, which inherited the least risks. Thus, they have changed their plans and proceeded with the least risky candidate instead of the architecture they planned to.

It has to be noted, that a high Risk Priority Number does not mean that teams are not able to achieve the specifications. It means that it will be more challenging to meet this specification compared to others. Thus, it is reasonable to follow up the specifications with a high RPN

first, since they might become exclusion criteria for the chosen architecture. Nevertheless, for the teams in the field study, it was obviously the best choice to proceed with the candidate with the lowest overall risk. The product development teams of the class 2.739 had a tough timetable and could not afford to loose time due to iterations or delays.

The two teams at the end of the field study had proceeded farther in the process and had reached a point for which the method was developed. They had already narrowed down their choice to one product architecture and elaborated a good idea of the later product. For them, the objective was to review of their product architecture, to identify, and eliminate potential deficiencies to the extent possible.

The team "Combination of Toothbrush and Toothpaste" did well and had a low Total RPN score. Nevertheless, they had to follow up the two specifications, which were identified to fall behind. They developed corrective actions and monitored those specifications. But it has to be noted, that only six specifications were left at that point. This leads to the following conclusion: It will never be certain that all objectives of the later product are properly covered by the specifications. The risks the not all objectives are expressed in the best possible manner remains.

The other team had chosen their final product architecture shortly before the risk analysis took place. Thus, they knew that a variety of issues was left they need to address. The overall risk score in the analysis was higher and more balanced (see Team "Adjustable Insulation Jacket", Appendix. p. 143). Nevertheless, they could identify the six most challenging specifications of their product architecture, out of overall 30 specifications. In addition, this team had scheduled extensive tests for the following day, and they particularly examined the specifications rank highest. Thus, they could identify shortcomings of the current architecture very quickly and changed details without loosing to much time. On the contrary side, hardly new actions were introduced by the analysis. The participants often answered the questions for the assessment or potential corrective actions by pointing to the test on the next day. Especially for the accessibility, they tended towards lower ratings since they felt very comfortable about their test. Thus, it would have been more useful to conduct the method afterwards. Nevertheless, they kept a certain eye on the challenging aspects of their architecture.

With the last two teams, a further aspect could be identified. For more successful procedure, it was crucial that the team had defined specifications prior to the analysis. The first teams rather had customer needs (requirements), which can be interpreted too broadly. For some specifications, the teams had already assigned a target value or had clear objectives in mind. This turned out to be extremely useful for the assessment. It allowed a more objective and fact-oriented discussion.

Overall, the method represented a valuable means for the teams to review their candidate architecture. Although the method was not perfect, the structured review and the encouragement to express concerns were well received among the team members. In the following the feedback they gave will be presented. A reflection of the method, e.g. regarding advantages and disadvantages, is described in section 6.4.

6.3 Feedback

The participants were asked to provide feedback of the field study, which will be presented in this section. First, the questionnaire is described (section 6.3.1). Afterwards the results gained by the survey are discussed (section 6.3.2). The received opinion of the participants in the field study is presented in section 6.3.3.

6.3.1 The Feedback Questionnaire

After the teams had conducted the analysis, the participants were asked to answer a feedback questionnaire and encouraged to provide additional comments. The questionnaire was developed to review the meeting and to improve individual aspects regarding its procedure. Additionally, benefits of the Specification Risk Analysis should be identified. It should help to measure the subjective opinion of the participant and thus, get an impression about the effectiveness of the method.

Overall, sixteen feedback forms were filled out. The form contains eight statements and five answer boxes ranging from “strongly agree” to “strongly disagree” (see Figure 6-2). The answer box in the middle is equivalent to an indifferent opinion.

	strongly agree				strongly disagree
(Prior to the meeting) We understood what information is needed to conduct the method.	○	○	○	○	○
The procedure was easy to understand and to follow.	○	○	○	○	○
The tools (worksheet, handout with assessment scales) were appropriate.	○	○	○	○	○
I understood the outcomes that the process yielded.	○	○	○	○	○
The outcomes of the process correspond to what I believed before we conducted the method.	○	○	○	○	○
The results will help us with the project’s progress.	○	○	○	○	○
The method imposes new actions we haven’t previously considered.	○	○	○	○	○
The method would have helped me in previous and similar projects I’ve done.	○	○	○	○	○

Figure 6-2: Feedback Questionnaire of the Field Study

The questionnaire addresses two domains: The first four questions investigate the procedure of the analysis. The second part concerns the results of the method and their utility.

The preparation of the method is addressed by the first question. It is investigated if the team members understood what was needed to conduct the method. This should ensure that they understood that their product architectures as well as the list of specifications are the input for the method. The next two questions address the procedure and tools of the method. It is questioned whether the procedure is easy to understand and the tools (i.e. worksheet, handout,

and scales) support the procedure in an appropriate manner. The last question addresses the outcomes of the method and if they are easy to understand.

The second part of the questionnaire addresses the interpretation of the results and their utility for the future procedure. The fifth question investigates the correlation between the results and the intuition of the participants. Afterwards, it is asked if the participants believe the results would be useful for their further procedure. The second last question addresses the phase of mitigation and whether new actions were imposed. The last question pertains the general utility of the method and if the risk analysis would have been useful in former projects.

6.3.2 Results of the Survey

In the following, only the results considering all participants will be presented. The individual ratings for each team can be found in the Appendix (section 9.4.6, p. 122 ff.). In order to get a better feeling for the results, the ratings are shown by means of a Boxplot diagram (see Figure 6-3). The questions of the questionnaire are listed on the horizontal axis; the level of agreement is presented on the vertical axis. The short, bold dash represents the median of the feedback ratings of all participants in the field study. Fifty percent of all ratings are within the large, blue box. The thin, black lines range from the most negative to the most positive rating (minimum, maximum). Thus, the reader gets an impression about the distribution of the ratings. In the Appendix (p. 149), Boxplot diagrams with the individual team ratings are shown.

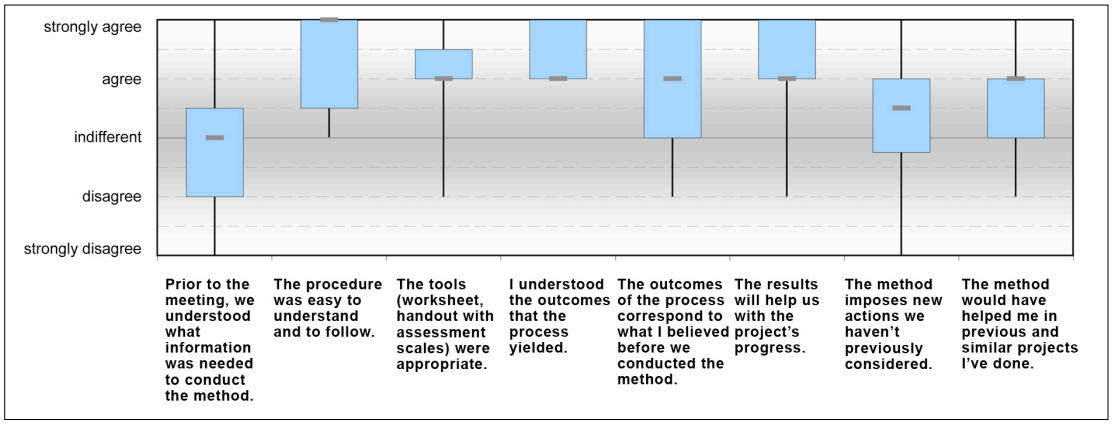


Figure 6-3: Results of the Feedback Questionnaire

Figure 6-4 shows the teams' received opinions evolving over the duration of the field study. Only the first four statements of the questionnaire are shown in this figure. The remaining ones will be shown in a separate graphic.

The answers regarding the first question, the preparation of the method, were the most diversified ones. The overall opinion showed a tendency between indifference and a slight disagreement. In order to interpret this result in the right manner, some facts need to be

repeated. For all teams, only the contact person was informed about the details of the analysis, assuming that he or she would inform the teammates in an appropriate manner.

Unfortunately, most team members were not informed well by their colleagues. This resulted into the fact that not all participants knew what was needed to conduct the method. The answers for this question ranged from strongly agree to strongly disagree (see Figure 6-3 or Appendix, p. 149). It was tried to improve the flow of information by explicitly announcing that the product architecture and their current list of specifications were needed. At the end of the field study, the teams understood the input of the method better than the first ones (see Figure 6-4).

The first team in the field study still had minor problems with the procedure. As mentioned previously, unnecessary information was continuously eliminated and the procedure was simplified to the extend possible. Thus, it was easier for the following teams to understand and follow the procedure. The change towards a parallel analysis rather than the analysis of a single architecture seemed to facilitate the procedure. The tendency in the statements showed a very strong agreement of later participants (see also Figure 6-3).

The third question investigated the appropriateness of the tools (i.e. the worksheet, the handouts, and the assessment scales). Although the scales were not refined during the field study, the worksheet was reprogrammed to address the needs of analyzing several architectures. Thus, it allowed a parallel analysis (cf. Figure 6-1). The ratings were split up afterwards to review the individual variants.

The fourth question, the last one regarding the procedure of the method, considered the outcomes of the method and if they were perceived to be easy to understand. Again, the tendency improved over the field study. No explicit actions were taken, but it is reasonable to assume that the outcomes are clearer and more definite if only one architecture is analyzed.

The overall tendencies of the questions, which regarded the procedure of the method, are shown in Figure 6-4 by means of the teams' average ratings. A continuous improvement could be identified.

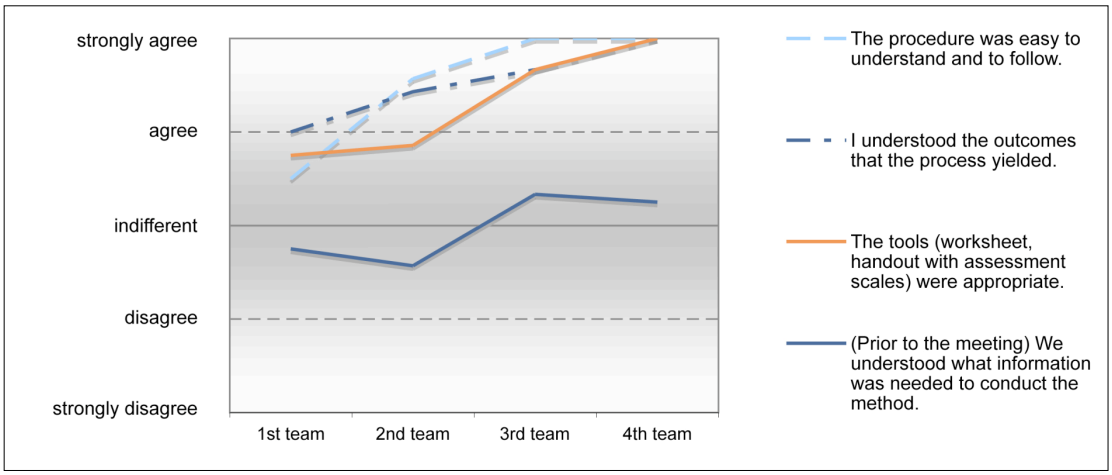


Figure 6-4: Feedback Regarding the Procedure of the Method

The second part of the feedback questionnaire considered the results of the method and their utility (see also Figure 6-3). The correlation between the results and the intuition of the participants was astonishingly high for most teams. The first team provided additional comments and said, that they were not sure if they had learned much more. However, they appreciated the structured review of their candidate architectures. Some participants of the field study were pretty surprised realizing that they hadn't followed up all requirements (see Figure 6-5, 3rd team). It was expected that the outcomes would correlate less with the gut feeling. However, this might not always be true.

Nevertheless, all teams strongly agreed that the results of the method would help them with their future procedure. The structured review and the knowledge, which specifications might become challenging to achieve, support the project's progress. All teams received this opinion.

Regarding the question, if the method imposes new actions, the average opinion of the team differs. The first and fourth teams did not believe that any new actions were introduced. For the other teams, the method imposed new actions or gave them a good idea where to start. One assumption can be made for this result: Although the first and the second team knew that they had to narrow down their architectures to a single choice, the results of the analysis were different for them. The first team already intuitively preferred the least risky candidate, whereas the second team was surprised that their favorite architecture was not the one with the fewest risk. For the third and the forth team, there was a similar situation. The third team realized that they hadn't followed up all specifications and gained some insights. The fourth team had scheduled a testing weekend the day after the analysis and considered this as already planned actions.

The last question addressed the experience of the participants and whether the method would have been useful in previous projects they have done. All participants agreed more or less strongly, that the method would have achieved benefits in projects they have done earlier.

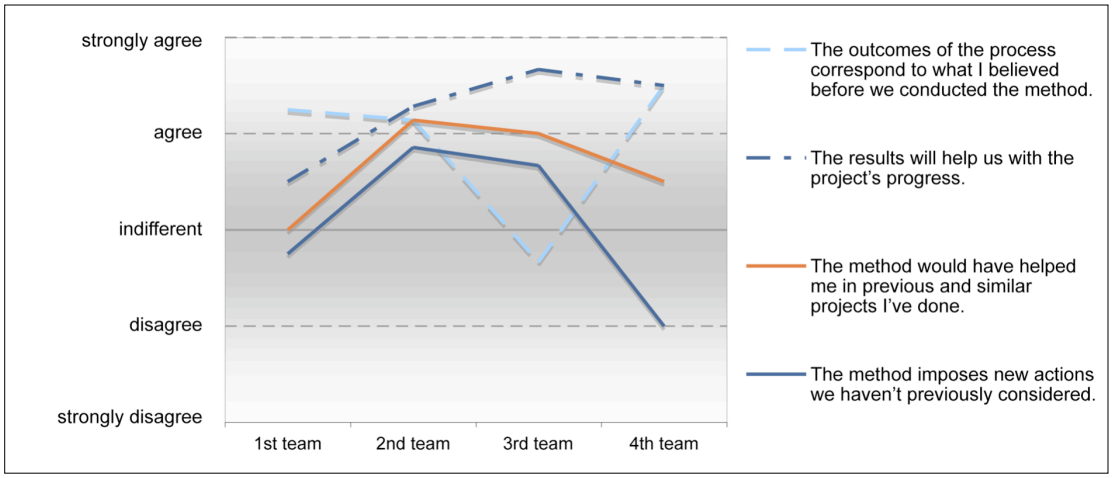


Figure 6-5: Feedback Regarding the Outcomes of the Method

6.3.3 Received Opinion of the Participants

Overall, the method got positive feedback. The feedback formed a basis for the iterative improvement process and, thus, a positive tendency in the questionnaires could be achieved (see Figure 6-4, Figure 6-5).

Figure 6-6 shows the average opinion of all participants. In order to get a better feeling for the results, the ratings were transformed into numerical values and the average was calculated. 100 % is equivalent to the scenario that all participants strongly agree, whereas -100 % would mean that all participants strongly disagree. The range in between should express the tendency in the statements. 0 % is the equivalence to an indifferent opinion.

The participants tended to understand what was needed prior to the analysis (18%). The relatively low score has been explained above: Establishing a contact person was difficult. In addition, communication within the groups could be improved. Most of the participants agreed that the procedure was easy to understand and follow (78 %). One student said it was "a very simple procedure" and thus "easier to wrap my mind around it [the analysis]". The tools were considered as appropriate and helpful (70 %), and the outcomes of the method were easy to understand (78 %).

Unexpectedly, the results of the method corresponded strongly with the intuitive believes of the participants. On average, they agreed with the statement that the outcomes correspond to what they believed before (58 %). If one looks at the individual replies in the questionnaires, one can see that the outcomes did not correspond for all participants with what they had believed before. One participant of the team "Combination of Toothbrush and Toothpaste" noted "I didn't realize we haven't followed up (…) [that aspect] at all."

Although the outcomes corresponded more or less with the intuition of the teams, they still believed to benefit from the application of the method. Most participants thought, that the results the process yielded would help them with the project's progress (68 %). One participant wrote: "After talks with you, and the professors, we are redefining our concept." Two reasons can be assumed therefore: First, the method presents a structured approach and imparts a good idea, which issues need to be addressed. Second, specific specifications, that might have fallen behind otherwise, are addressed. Even if the intuition of the team was correct for most of the specifications, it might not be correct for every single one.

As discussed earlier, the participants agreed that the method imposes new actions (33 %). However, this statement was not as strong as the other ones have been. Nevertheless, the method forms a good approach for a structured review and gives a good idea where to start. A participant said "We've already scheduled intensive tests for the next day, so the method does not impose new actions for us. However, it gives us a good idea on which aspects we need to concentrate." Thus, most participants believed that the Specification Risk Analysis would have helped them in previous and similar projects (48 %).

The feedback questionnaire helped the author to identify deficiencies of the current version of the Specification Risk Analysis. Thus, certain aspects could be critically reviewed and improved. The insights gained by the field study and the conclusions drawn from the feedback questionnaires will be discussed in the next section.

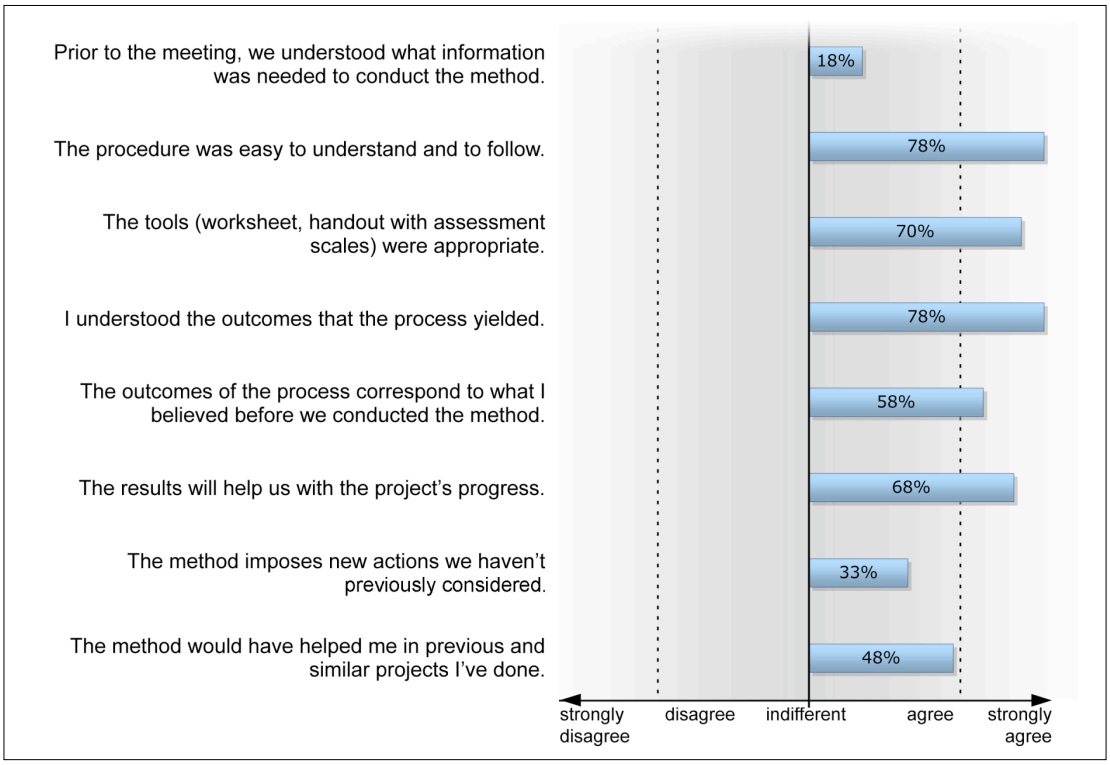


Figure 6-6: Average Results of the Feedback Questionnaire

6.4 Conclusions

This section seeks to review the method developed, as well as the results and insights gained by means of the field study. The following points will be critically discussed:

- The achievement of the field study's objectives
- The execution of the field study
- Important findings from the field study
- Advantages and limitations of the Specification Risk Analysis

The field study intended to achieve two objectives. First, the Specification Risk Analysis Method should be refined. Second, the analysis should assist the development teams regarding the management of their key challenges.

The experiments sought to obtain a practical application of the method. Thus, current deficiencies and room for improvement could be identified. The most fundamental step was the elimination of over-information: The procedure of the method was simplified from meeting to meeting. In addition, the spreadsheet was modified to accommodate the analysis of several architectures. The feedback of the participants helped to revise the procedure.

The second objective of the field study was to help the teams of the class 2.739 regarding their key challenges. The method offered them a structured approach in order to review their architectures. At the beginning, it was not designed to analyze several architectures. However, this turned out to be reasonable for the groups since it helped them with their further procedure. It formed a valuable basis for the architectural choice. Although for most teams not all specifications were analyzed, key challenges and potential shortcomings of their products could be identified.

Overall, the field study yielded many insights. The execution was not perfect and some aspects can be improved. The meetings with the groups were scheduled in the short term and thus, often night shifts were necessary to prepare the meetings. It would have been better to contact the teams via a contact person or a project manager. Then, meetings could have been scheduled with more preparation time. This aspect could not be changed within the field study. Nevertheless it was good, that at least the engineers in the teams could be contacted.

The time for the individual meetings was very short, since it was promised that the meetings would take about an hour. Thus, for most teams, not all specifications could be analyzed. The analyzed specifications were usually derived from customer needs with high importance ratings. However, for a more meaningful discussion, probably all specifications should be taken into account.

Within the field study it was observed that a parallel assessment of several product architectures was more convenient. It would have been hard to anticipate that and re-programming the assessment sheet was only possible after the feedback from the first team.

On the positive side, the field study revealed some important findings. First of all, the field study showed that the method could compare several preliminary architectures. Although some limitations have to be taken into account, e.g. that developing corrective actions may not be appropriate, valuable insights for the further procedure may be gained. The application at a later point in the field study disclosed some advantages for the analysis of a single architecture. The analysis is more accurate and concentrates on specific issues. It allows a very focused, concrete discussion and review of the current product architecture.

In addition, the field study discovered that specifications were much more appropriate for the assessment than sheer customer needs, also named requirements. Requirements can be interpreted too broadly, whereas specifications are more accurate and aim towards a defined target. It was crucial for the success of the method, that specifications were defined. Furthermore, it was useful if the team had assigned target values or had clear objectives in mind.

As already described for other methods in product development, it was observed that the size of the team does not contribute significantly to the results. Nevertheless, it is recommended that at least three participants with different backgrounds conduct the analysis. The discussions in cross-functional teams were manifold and more fruitful. Especially for the corrective actions, it could be observed that people from different fields had different points of view and thus more “creative” solutions could be obtained.

Finally, it was documented that the method helps designers to minimize the risks of not achieving specifications and that benefits can be achieved. The teams that conducted the

Specification Risk Analysis performed better than their fellows in the course. This is a good indicator for the effectiveness of the method. Although it has to be noted that other factors, e.g. personal commitment and time spent, also influence the groups' performance in class.

The method includes a number of advantages for design teams. First of all, it offers a structured approach to review the current architecture(s) and to align the team's mental models. Moreover, the specifications are reviewed and it is ensured that no requirement falls behind or isn't followed up. By means of this review, it is analyzed if all specifications are up-to-date: In the field study some specifications were modified, some were described in more detail. Sometimes new specifications were introduced or obsolete ones were eliminated. The assessment and ranking of the specifications then helps the team to identify critical issues and challenges they might face. In addition, the method supports the development of corrective actions, responsibilities, and completion dates. Thus, it provides a good mean to eliminate potential product deficiencies with a rational effort.

On the negative side, the method only takes aspects into account that are described within the specifications. If something is not documented in the list of specifications, it is still forgotten. In addition one has to be very carefully about the assigned ratings and calculated priority numbers. A sensitivity analysis is highly recommended, and furthermore, the team must not rely blindly on the numbers.

One aspect sometimes falls behind in Risk Management. Only because risk management is conducted - whether it is a generic approach or a method like the presented one – it does not mean that something can't go wrong. Alertness and awareness are probably the most required characteristics to prevent the occurrence of risks. The Specification Risk Analysis only presents a mean for a structured and systematic examination.

Moreover, architectural decisions affect more than just the technical product performance. They affect dozens of issues that are linked to it, e.g. issues regarding production, product change and variety, standardization, the management of product development [ULRICH 1995]. Other risks in product development will still remain, for example the ones related to the process, the production, or the environment.

6.5 Reflection regarding the Fulfillment of the Requirements

During the analysis of the state of the art in chapter 3, requirements and recommendations for the method to develop are derived. This section intends to reflect their fulfillment and, if possible, present evidence gained in the field study.

The first requirement ("The method is a tool for risk management.") is achieved since the whole method seeks to identify and manage risks. It is tailored to the risks of not meeting product specifications (*REQ 3*). By means of the method a product architecture can be analyzed in the Embodiment Design phase (*REQ 24*).

Because of the pilot test and the field study, the procedure could be continuously refined. The first draft contained too much information and turned out to be confusing. Therefore, the method was simplified until the current method was achieved (cf. chapter 5). This was also

perceived by the participants in the field study who strongly agreed that the procedure was easy to understand and to follow (see Figure 6-3). Thus, the requirements of clear objectives, steps, and key elements are fulfilled (*REQs 2, 8 10*).

With the FMEA as the starting point of the development, the Specification Risk Analysis also follows the five phases of risk management (see section 3.2.3, *REQ 4*). By means of the field study the phases Initialization, Identification, and Assessment & Priorization could be executed. The remaining phases Mitigation and New Situation & Monitoring were only discussed with the participants but not executed.

The Initialization phase was improved so that by the end of the field study more participants understood what was needed to conduct the method (see Figure 6-4). Activities that have to be conducted in advance of the method's application (*REQ 6*) are described in section 5.2.1. Additionally, a handout and a spreadsheet were developed to accommodate the analysis (*REQ 7*). This was well received by the participants who thought that the tools were appropriate (see Figure 6-4). The field study also showed that it is beneficial if the participants have different backgrounds (*REQ 5*, see section 6.2.2).

In the Identification phase, the analyzed architectures were visualized by means of drawings and sketches (*REQ 9*). This turned out to be very valuable and supported discussions. The list of specifications was used to identify the risks of the architecture (*REQ 12*). Unfortunately, not all specifications could be analyzed in the meetings due to time constraints.

For the assessment of risks, the probability of occurrence was estimated by means of the Accessibility and Feasibility ratings (*REQ 13*). The Contingency Rating estimated the effectiveness of existing mitigation measures (*REQ 23*) and therefore the impact if the analyzed architecture could not meet the specification as intended (*REQ 13*). All three key figures were estimated by means of 1…10 scales (*REQ 22*). This turned out to be very reasonable since it allowed the assessment of subtle differences between the individual specifications. Afterwards the Risk Priority Number could be calculated and the risks were prioritized (*REQ 14*).

In the field study, mitigation measures were briefly discussed. If the teams analyzed various architectures, the only future action assigned was the collection of additional information. For the teams that analyzed a single architecture, more mitigation actions were described (*REQ 15*). Unfortunately, no responsibilities or completion dates were assigned since not all team members took part in the analysis (*REQ 16*). Also requirements 17 to 19 (measurement of the effectiveness of actions taken, monitoring, indication of final status) could not be executed although the method describes these steps. Although this was not proven in the field study, the method seeks to fulfill these requirements.

The teams thought that the results will help them with the projects process and that the method would have helped them in similar projects they have done previously (see Figure 6-5). This indicates that the method helps to understand characteristics regarding a product's risks in a better manner (*REQ 21*). Additionally, it has a positive effect on how the team performs its work (*REQ 20*) since they get a good idea on which aspects they need to concentrate in the future.

In general, the method fulfills its objective to manage risks proactively (*REQ 11*). By means of the field study some aspects of the method could be executed and improved. It would have been useful to have a second meeting with each team in order to follow up the analysis and conduct the remaining steps of the method. Then, the mitigation and monitoring phase could have been executed.

6.6 Summary

This chapter described the execution and results of the field study conducted with teams from a product development and design course at MIT. First, the objectives of the field study were described (section 6.1.1): It sought to achieve a practical application of the method and intended to assist the design teams with the key challenges of their product. Afterwards, the setting and methodology of the field study as well as its execution were presented (section 6.1.2, section 6.1.3, section 6.1.4).

The gained data was analyzed in section 6.2. Two potential applications could be identified (section 6.2.1). In section 6.2.2, several improvements for the procedure were identified, e.g. the refinement of the spreadsheet or a simplified description of the method. The results, which can be achieved by means of the Specification Risk Analysis, are discussed in section 6.2.3. The method offers a structured approach to review a product architecture and identifies so far unseen challenges. A side effect of this structured review is also the update of the specifications. Overall, the method helps teams to manage and mitigate specifications risks inherited in their architecture.

The participants of the field study were also asked to provide feedback by means of questionnaires presented in section 6.3.1. Afterwards, the gained data was discussed. A positive trend and the improvement of the method are shown (section 6.3.2). The received opinion of the participants was presented in section 6.3.3.

In section 6.4, conclusions regarding the procedure of the field study and the method itself were drawn. The field study was reviewed and important findings were described. Moreover, the method was critically analyzed regarding its advantages and limitations. It was emphasized that the mere execution of risk management does not indicate nothing could happen anymore.

Section 6.5 reflects the method and the field study regarding the fulfillment of the requirements. It was shown, that all requirements could be fulfilled. If possible, findings from the field study and the feedback of the participants were presented as an evidence.

Aspects that were not addressed in this thesis are described in the outlook in the next chapter. In addition, personal experiences related to the stay at MIT are described.

7 Outlook and Reflection

In this chapter, the thesis is reflected and an outlook for future research is given. The first section (7.1) analyzes the Specifications Risk Analysis from a perspective of Lean Product Development. In addition, potential further improvement is identified. Possible future directions for research in general are described in section 7.2. A personal reflection of the stay at MIT rounds off the chapter (section 7.3).

7.1 Specification Risk Analysis

The Specification Risk Analysis represents a tool that offers a structured approach to analyze one or several product architectures regarding their key challenges. The method adopts the matured procedure of the FMEA and tailors it to the needs of specification risks and the phase of embodiment design. It helps the designer to identify potential deficiencies of the later product regarding its specifications. The specifications are derived from the customer needs, and thus, directly express the customer value. Customer needs represent all requirements a product needs to fulfill: e.g. the requirements of the end product's costumer, the requirements of stakeholders, or legal requirements.

Lean Product Development emphasizes a critical review of designs before they are completed. By means of the Specification Risk Analysis, potential shortcomings of the later product can be identified, prioritized, and mitigated. Therefore, not only the paradigm of "creating customer value" is addressed by means of the method, but also the other principles of Lean Product Development. The method seeks to align value-adding activities and to achieve perfection in value creation. Specifications that might become exclusion criteria for the current design are identified in an early phase.

The method emphasizes the development of corrective actions and fallback solutions, as well as the assignment of responsibilities and completion dates. Thus, time and cost-consuming late term changes can be avoided. As already mentioned at the beginning of this thesis, a product development team acts lean if it achieves high quality within low costs, e.g. by eliminating non-value adding activities, continuous improvement of all involved processes, etc. It is highly beneficial if it anticipates risks and masters the challenges of product development at low costs within little time. Little development time, low cost, and high quality can be seen as the key drivers to the success of a product development system. The method presented aims to addresses all the dimensions.

Similar to the extensive study in the automotive industry (cf. section 2.3.3), the study with the product design teams at MIT showed that not all specifications were followed up in an equal manner. By means of the Specification Risk Analysis, deficiencies of the current architecture and specifications that had fallen behind were identified. Thus, the product architecture and the specifications were systematically reviewed and improved. This practical approach was well received in the field study.

On the contrary side, the method inherits some room for improvement. The importance of specifications is not taken into account at the moment. This is currently achieved by the Feasibility Rating and the likelihood that the architecture will meet the specification. However, there might be better ways to measure this, e.g. by introducing a fourth assessment scale considering the importance of a specification. For the team "Adjustable Insulation Jacket" in the field study, only the most important specifications were analyzed. The specifications were selected by means of their assigned importance rating, a task that was conducted earlier in the course. Thus, an efficient analysis could be conducted while still achieving the promised meeting time of one hour. This might be an important aspect for more complex products if it is not possible to analyze every specification. However, potential benefits and deficiencies (e.g. like the oversight of risks) could not be investigated in much detail.

The Contingency Scale estimates the consequences in case the specification cannot be met. This is achieved by assessing the quality of other options. It estimates the performance of the alterative, its cost-effort-ratio, and its easiness of replacement. However, to what extent the specification cannot be met and how this influences the consequences, is not taken explicitly into account. It is not guaranteed that this is the best approach to measure the severity of the consequences.

In future, it would be beneficial to investigate the application of the method within a project in industry. It could be analyzed whether the complexity of requirements might form a problem or if a potential cooperation with existing requirements management tools might be possible. Unfortunately, due to the time constraints, this was not possible within this thesis.

In addition, it would prove worthwhile to investigate best practices for the initialization and the follow up of methods in general. Whereas the "inner phases" of methods are well understood, the starting and follow up phases are less explored. For the Specification Risk Analysis, for example, it might be useful if one person does a re-assessment of the ratings every other week and presents the results to the group when appropriate. Thus, not all team members need to conduct the analysis together but can discuss the critical ratings as a group. Nevertheless, there is a broad variety of future tasks.

7.2 Future Research

Some aspects regarding future research have already been addressed in the previous section. This section will discuss other potential fields of interest that are not related to the Specification Risk Analysis.

Risk management in general offers promising approaches to reduce the likelihood of performance deviations in product development. However, risk can be interpreted much broader than only in the sense of not achieving specifications. In section 2.3.2, an overview of some risk types is given that might also be addressed in future research.

To the author's knowledge, no quantitative method for risk management exists in product development so far. Various authors identify this as a future challenge that should be addressed. However, no method has been developed. It has to be questioned if a quantitative

assessment is really the preferred variant. Does the effort to get the necessary input data justify the benefits of quantitative risk management?

The thesis suggested the FMEA or respectively the Specification Risk Analysis as a tool to anticipate risks in product development. However, no generic model to access the value of risk management exists to measure its potential. A detailed study of its effects might possibly achieve new insights. By means of the Specification Risk Analysis, this could be empirically proven, e.g. by the percentage of performance deviations from the originally identified product specifications. But also other methods may be chosen as a basis for such an analysis. An additional observation of this research has to be noted: Though a variety of generic risk management frameworks in product development exist, practical and easy applicable tools are still missing.

This thesis has shown that the highly matured procedure of the FMEA can be adopted for various purposes. The fundamental procedure of the method is similar to the generic problem solving approach engineers love to follow. The FMEA inherits far more potential than for the analysis of quality issues or specification risks. It might be possibly adapted for other fields as well, e.g. for manufacturing risks, technology risks, etc. Especially if the assessment categories are tailored to the specific needs of the situation, significant benefits may be achieved. Nevertheless, those benefits have to be weight against potential disadvantages, which have been discussed in section 3.2.1.

One focus of this work was the perspective of Lean Product Development. This philosophy offers interesting insights: It mitigates the former conflict of time, cost, and quality in product development and overrides thinking barriers in the fields of design and production. But besides its five principles, Lean Product Development is not understood very well. Value Stream Mapping is probably the best known tool. Various authors investigated facets of Lean Product Development, for example: the creation of value, the elimination of waste, or the improvement of flow. Nevertheless, some aspects remain very fuzzy. For example, “customer value” is a very abstract idea and could be defined or measured in a better way.

Although Lean Thinking is an excellent approach, the author doubts that it is a stand-alone solution in product development. So far, no generic procedural approach has been for Lean Product Development. Little is known about its application outside the Toyota Motor Company. And it would be interesting to learn more about best practices outside the company of its founders.

7.3 Personal Reflection

In this section, I review my own experiences. Its purpose is not only a personal reflection, but it may also give some insights for people involved or future students at MIT.

The past seven months have been full of new impressions and experiences. And I have to admit that some of them were quite unexpected. Nevertheless, my stay in the United States and at the Massachusetts Institute of Technology has been an interesting experience – teaching me a lot about myself, and what I value in life.

The time spent preparing for my stay here was quite busy with organizing and managing various issues. Financing my studies, writing final exams, applying for scholarships, dealing with visa regulations, health insurance, etc., took a lot of time. My advisor Martin Graebsch kindly provided a lot of extremely helpful recommendations for the preparation of this stay. Additionally, I wrote my last term paper in English to train my scientific language skills. This turned out to be very valuable. Looking back, it would have also been advisable to study some literature in advance. However, there was little time left.

When I arrived at MIT in late autumn, Prof. Seering and my colleagues from the Lean Product Development Group gave me a warm and friendly welcome. At the beginning, I met Prof. Seering and Eric Rebentisch almost weekly, and our discussions were fruitful and valuable. Martin Graebsch provided great feedback. He definitely saved my Christmas vacations with an encouraging phone call. I couldn't have had a better advisor at my home university.

During spring term, faculty and students were very busy. Nevertheless, Professor Seering always tried to meet with each of his students on a regular basis. Since I also joined meetings of another group for a while, I came to recognize that this is a special arrangement at MIT, and I highly appreciate it.

However, adapting to the different working style at MIT took me quite a while. The attitude toward research is different, the pace is much faster, and the opportunities here are so manifold that they are almost overwhelming. While you start your diploma thesis with a defined problem at the Technical University of Munich, MIT offers you the freedom to choose a subject on your own. Having this choice is both a blessing and a curse, especially if you have only six months to do all the work.

At the beginning, it took me quite a while to interpret the American feedback culture. While I was used to a relatively straightforward and broad range of feedback statements, it was challenging to capture the more subtle differences here. Moreover, it was difficult to find students to discuss ideas every now and then, so that I wasn't working completely on my own all the time. Students at MIT are so busy with their research, classes, and homework, that they barely have time left for informal discussions or socializing. Soft skills are less appreciated and thus sometimes left behind. I'm glad that there are exceptions.

My colleagues were terrific and they considered my as one of the Silo group quickly. Nevertheless, it took me quite a while to get to know other students. The gatherings of the Euro Club were pleasant, and I made some new friends. Fortunately, MIT offers at least one day off

every month. You should take the opportunity to see something else on these long weekends. Imagine, New York is just a $15 bus ride away! I can only recommend future visiting students to spend at least one more month here. Take the opportunity to visit some of the beautiful places in this country.

On the personal side, I must admit that not every day was a sunny day. I assume that finishing your studies is always an experience that challenges you in many ways. There were days that were quite cloudy, when I couldn't see a happy ending, or when I mistrusted my ambition to become an engineer. Those days were definitely a very hard time. I have always been a trooper, and I've never expected it to be easy. However, I also didn't expect it to be that hard sometimes.

Nevertheless, my predecessors from my home university were right in saying that they experienced two sides during their stays. At this point, I've become adjusted to the culture and the environment here. It was a gradual evolution: I got a clearer idea what I wanted to do, and I began to enjoy my work again. Yes, I am truly an engineer. Probably not the most conventional one, but I rather regard that as an advantage.

In the future, I guess I will slightly forget the cloudy days and rather see the positive things this challenge kept for me. Even now, I can tell that I gained some very good insights about me and where I see myself in the future. And maybe there are even more.

8 Summary

This thesis investigated the application of the Failure Mode and Effect Analysis (FMEA) as a risk management tool in Embodiment Design. The FMEA is a well-known method in engineering that has been applied to address quality and technical reliability issues. However, its basic procedure is very similar to the fundamentals of Risk Management.

At the beginning, a literature review was conducted in order to enhance the understanding of risks in the phase of value creation in general and in embodiment design in particular. A brief overview over risk types and categories was presented. In addition, it was argued that the final state of a product is determined by how successfully requirements have been incorporated into a solution (cf. chapter 2).

The FMEA and Risk Management were analyzed regarding their similarities and differences. Both follow a highly similar procedure and seek to reduce the likelihood and consequences of performance deviations. For a product, the performance objectives are expressed by its specifications. Until the product architecture is not defined, it is not known whether the product to develop will meet those specifications or not. Since the product architecture is elaborated in the phase of Embodiment Design, the characteristics of this phase were analyzed from a perspective of risk management. During the literature review, requirements for a method to manage risk of not achieving product specifications were derived (cf. chapter 3).

Afterwards, the tool for risk management was developed. It was based on the procedure of the FMEA and adjusted to the derived requirements. Three new dimensions for assessing the risks were identified and developed (cf. chapter 4). The final version of the method was named Specification Risk Analysis: It formed an approach to address and manage risks of product architectures regarding not achieving specifications (cf. chapter 5).

Furthermore, the method was continuously refined by means of interviews, pilot tests, and a field study. The field study was conducted with four design teams of a product development and design class at MIT (cf. chapter 6). The fundamental objectives were to identify improvement opportunities for the Specification Risk Analysis and to help the teams with a structured review of their products to develop. Important findings could be derived from the field study. It was documented that the method provides great benefits. In general, the Specification Analysis seeks to mitigate potential deficiencies. It helps development teams to concentrate on core challenges while still monitoring a variety of risks. Moreover, the method assigns corrective actions, responsibilities, and completion dates. Applied in a correct manner, the method guarantees a follow up of the assigned tasks.

Nevertheless, not all inherited risks in a product architecture can be addressed by means of this tool. The method focuses on risks of not achieving specifications. It does not take other potential occurrences into account (see chapter 7). Additionally, it has to be noted that risk analyses – no matter how sophisticated – will always be inherently incomplete. “One can never know completely what one does not know” [PIDGEON 1998].

9 Appendix

9.1 References

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9.2 List of Figures

Figures that do not contain any references were created by the author.

9.3 List of Tables

Tables that do not contain any references were created by the author.

9.4 Attachments

9.4.1 List of Requirements

9.4.2 Scheme of Risk Management Frameworks and the FMEA

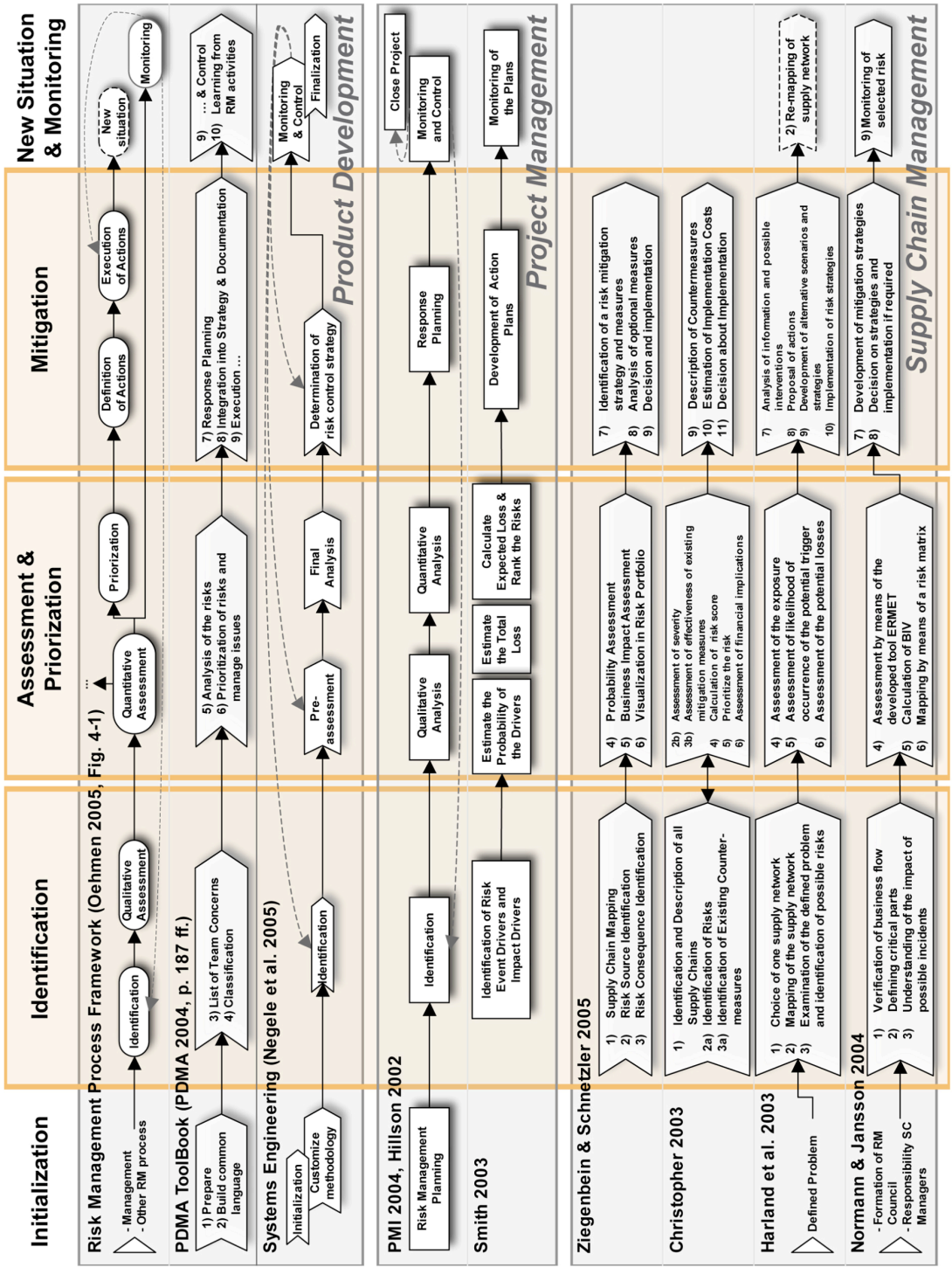


Figure 3-1: Overview over Existing Risk Management Frameworks, p. 21

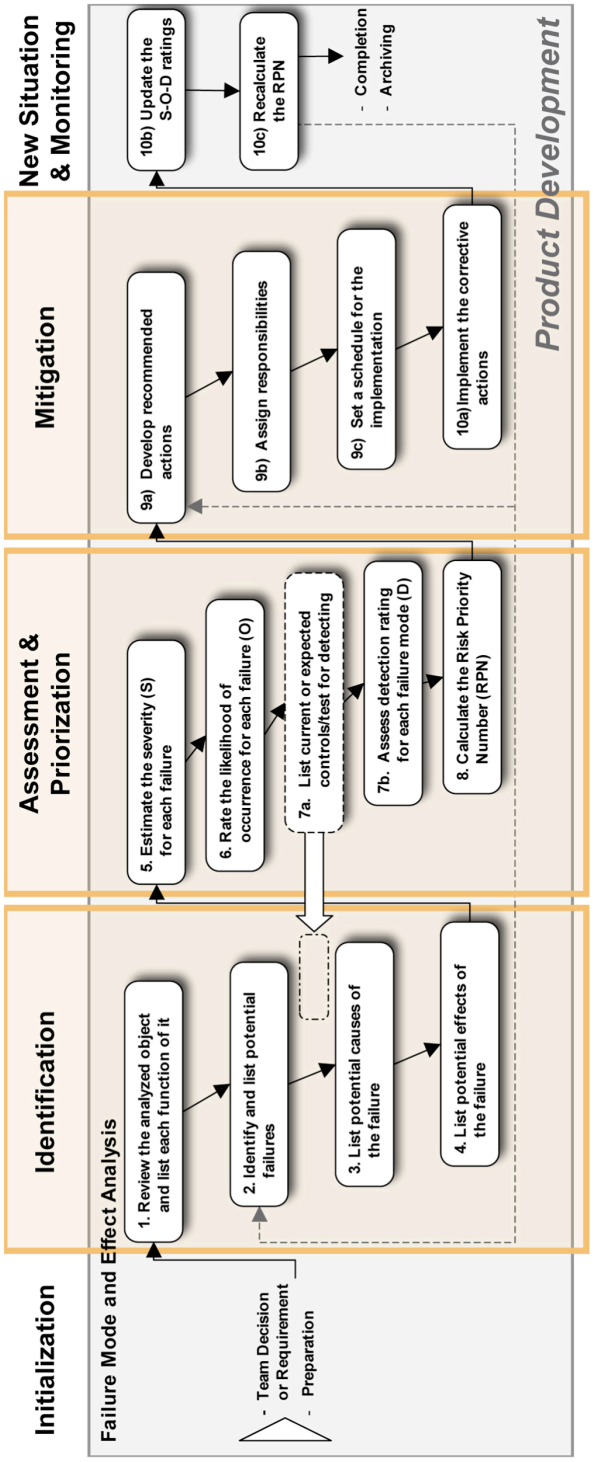
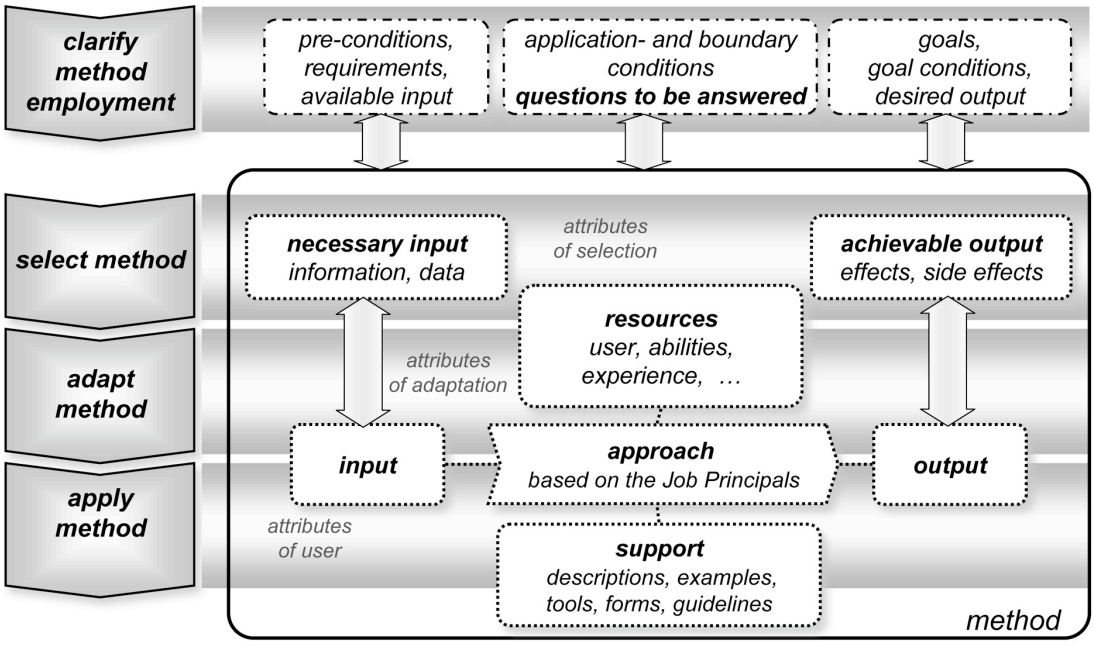


Figure 3-5: The Schema of the Failure Mode and Effect Analysis, p. 37

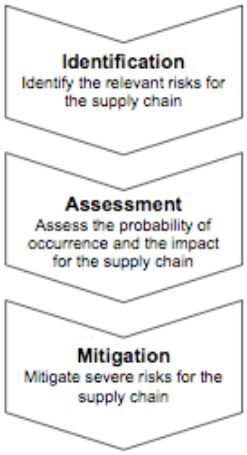
9.4.3 Munich Methods Model



Model for Describing and Applying Methods [Braun & Lindemann 2003]

9.4.4 FMEA-based Concept and Assessment Scales of the Experiment with Supply Chains

FRAMEWORK FOR RISK MANAGEMENT IN SUPPLY CHAIN MANAGEMENT



Step 1: Supply Chain Mapping
Step 2: Risk Source Identification
Step 3: Risk Consequence Identification

Step 4: Probability Assessment
Step 5: Business Impact Assessment
Step 6: Risk Portfolio

Step 7: Risk Mitigation and Strategy
Step 8: Analysis of Optional Measures
Step 9: Decision and Implementation

[ZIEGENBEIN & SCHNETZLER 2005]

THE 10 STEPS OF FMEA (ADAPTED TO RISK MANAGEMENT)

1. List each requirement of the analyzed object
2. Identify and list potential risks
3. List possible potential causes or mechanisms that may lead to the risk
4. List potential consequences of the risk
5. Estimate the severity of the consequences (S) for each risk
6. Rate the probability of occurrence for each risk (O)
7. List current or expected controls/test for detecting a risk
   Assess the detection rating for each risk (D)
8. Calculate the Risk Priority Number for each risk: RPN = S x O x D
9. Develop recommended actions for the risks
   Assign responsibilities to appropriate parties and team members
   Set a schedule for implementing the actions
10. Implement the corrective actions
    Update the S-O-D ratings and calculate the "Resulting RPN"

Claudia Wagner (claudiaw@mit.edu) Dec 15th 2006

POTENTIAL ASSESSMENT SCALES

Probability of Occurrence

Rating	Verbal description
1	Almost never, the risk is very unlikely to happen.
2/3	Never to rarely (relatively low probability)
4/5/6	Rarely to eventually (medium probability)
7/8	Eventually to likely (high probability)
9/10	Almost certain (very high (probability)

Severity of Consequences

Rating	Verbal description
1	No effect
2	Very minor (only noticed by very discriminating customer)
3	Minor (affects very little of the analyzed system; noticed by the average customer; minor annoyance)
4/5/6	Moderate (customers are annoyed or dissatisfied)
7/8	High (causes a loss of primary function; customers are dissatisfied, threat to customer relationship)
9/10	Very high and hazardous (product becomes inoperative; customers are angered; threats to security/safety)

Detection

Or: "Effectiveness of already implemented mitigation measures"

Rating	Verbal description
1	Almost certain
2	High
3	Moderate
4/5/6	Moderate (most customers are annoyed)
7/8	Low
9/10	Very remote to absolute uncertainty

Claudia Wagner (claudiaw@mit.edu) Dec 15th 2006

9.4.5 Handout and Procedure for the Field Study

Note that in the handout the term candidate or product architecture was replaced by the term concept. This results from the course lecture, which interprets concept much broader. The different interpretations of the term concept have already been described in section 2.1.

HANDOUT "CONCEPT RISK ANALYSIS"

Team: Adjustable Insulation Jacket
Date: Apr 18,th 2007

AGENDA

3.00 - 3.05	Brief Introduction
3.05 - 3.40	Risk Assessment
3.40 - 3.55	Analysis of the results and short discussion regarding future tasks
3.55 - 4.00	Feedback

Recommended further procedure:

- Detailed review of the gained data
- Implementation of recommended action

OBJECTIVE AND EFFECTS

The method aims to assess and manage risk of not achieving product specifications. The basic idea is to recognize challenges and possible risks early in the design process in order to minimize time and cost-consuming changes in a later phase.

It helps the design team to identify and document product specifications that might become difficult or 'risky' to achieve. Another output is a list of corrective actions, assigned responsibilities and completion dates.

PROCEDURE

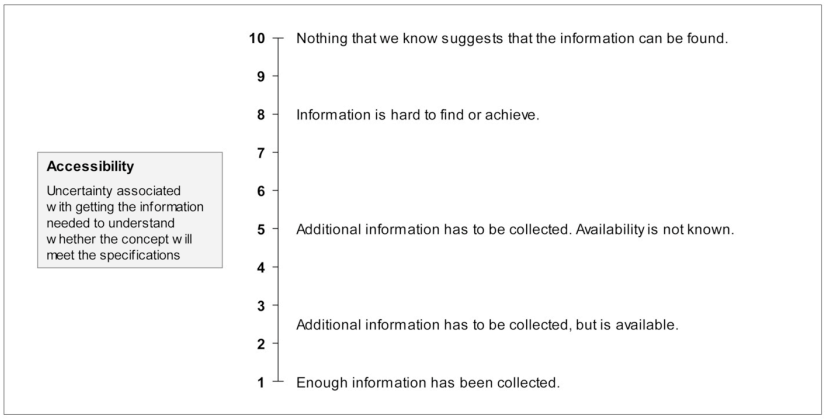
1. **Review the concept**

2. **List the product specifications of the analyzed concept**

➢ Answer the following questions (3-5) for each product specification ➢

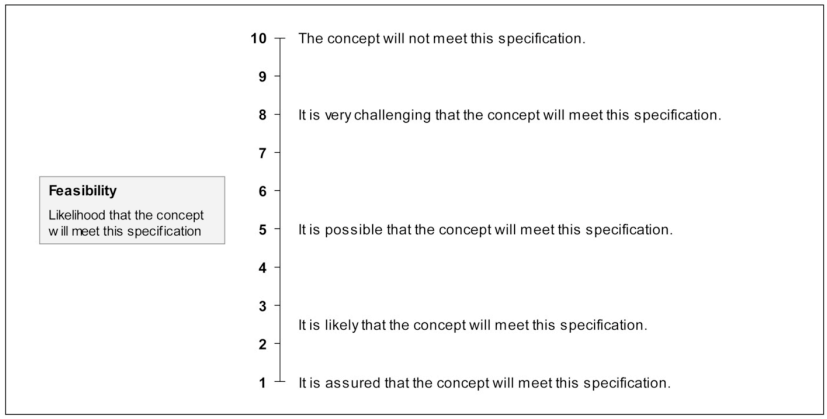
3. **How difficult is it for you to get the information needed to understand whether this concept will meet the product specification?**

Regard the given constraints of time and money!



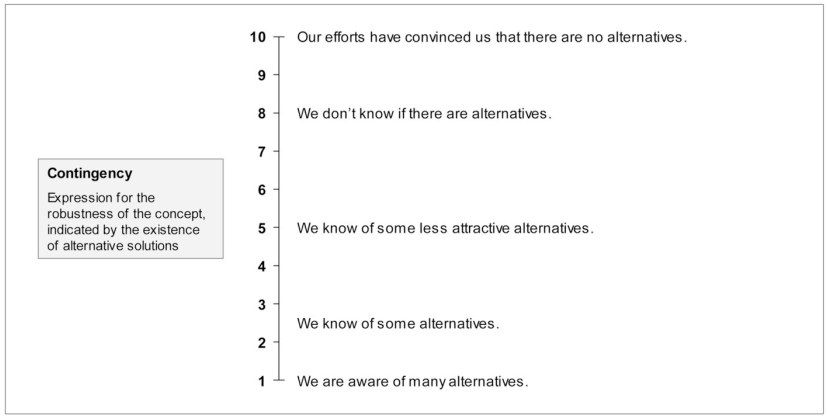
Assessment Scale for the Accessibility Rating (A)

4. Based on our engineering knowledge, how likely is it that we will meet the product specification with this concept?



Assessment Scale for the Feasibility Rating (F)

5. In case this concept does not meet the product specification, do you know of alternatives?



Assessment Scale for the Contingency Rating (C)

6. **Calculate the Risk Priority Number for each product specification: RPN = A x F x C**

7. **Prioritize the product specifications by means of the RPN**

8. **Develop corrective actions**
   Assign responsibilities for each action to appropriate parties and team members
   Schedule the implementation of actions

   Corrective actions should be developed first for the most severe risks.

   The recommended activities may address one or more of the following aspects:
   - Achievement of additional information (e.g. literature review, tests, surveys, ...)
   - A reviewed estimation of the feasibility (e.g. due to calculations, simulations, …)
   - Development or improvement of alternative solutions

9. **Implement the recommended actions**

WORKSHEET (EXAMPLE)

No.	Specifications			Accessibility (verbal description)	Accessibility Rating (A)	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN	Re ac
	Metric	Value	Unit								
1	Presence of Harmful Bacteria	*tbd* (better than existing solutions)	ppm over a certain time period								
2	Liquid / Gel Volume	<3	Oz								
3	Overall Size (if includes liquid/gel)	Fits 1qt Bag	Inches								
...											
									Total RPN	0	

N	Recommended action(s)	Responsibility	Completion Date	Actions taken	Updated Accessibility Rating (A)	Updated Feasibility Rating (F)	Updated Contingency Rating (C)	Resulting RPN

LIST OF SPECIFICATIONS

No.	Specifications				
	Metric	Unit	Value	... Derived from the Customer Need	Imp.
1	Insulation level (Thermal Resistance range) is adjustable	R-value ((square meters x °C)/watts)		adjusts heat loss from the body	5
2	Multiple levels of insulation in one layer			is made of few layers	5
3	Total Mass	Kilogram		is light-weight	5
4	Subjective			is comfortable	5
5	Elasticity of the fabric	Young's modulus		is close-fitting yet unrestricting	5
6	Air flow per square meter per time	Meter3/meter2/time		allows ventilation to sweat prone areas of body	5
7	Maximum Length of loose item	Metre		secures all movable parts ie: strings, flaps	5
8	Industrial standards tests	Binary		is reliable and durable	5
9	Elasticity of the fabric	Young's modulus		preserves it's characteristics during movement	5
10	Provides Maximum Insulation (Thermal Resistance) Level	R-value ((square meters x °C)/watts)		is warm (this is vague and non-descript)	5
11	Unit Manufacturing Cost	US $		is affordable for consumer	4
12	Time required for adjusting insulation level	Seconds		is quick to use	4
13	Number of steps required			is simple to use	4
14	Material dependent	Wool		is composed of material that offers microbial protection	what should it be?
15	Length in the front	Metre		is a cut to allow complete and unhindered leg motion	4
16	Insulation level (Thermal Resistance)	R-value ((square meters x °C)/watts)		thermally insulates the shoulders and lower back	4
17	Insulation level (Thermal Resistance)	R-value ((square meters x °C)/watts)		thermally insulates the head and neck (do we really want this?)	4
18	Sound due to fabric friction	Decibels		is quiet when rubbed against itself	4
19	Subjective			is stylish and fashionable (is this still applicable?)	4
20	Packing volume	Metre3		is stored easily	3
21	Wind permeability of material (Fraser Air Permeability Test)	CFM		is wind-resistant/ wind-proof	3
22	(Spray Test) Amount of water-force material can withstand	% / PSI		is water-resistant/ water-proof	3
23	Time	Seconds		is quick drying	2
24	Hypoallergenic			is suitable for sensitive skin	3
25	Abrasive grain size	CAMI		feels comfortable against the skin	3
26	Water vapour transmission rate	Grams/square meter per 24 hours		is breathable (THIS SHOULD BE HIGHER!!!)	3
27	Cleaning, Maintenance and Storage instructions/requirements			can be easily maintained	3
28	Total Pocket Volume	Metre3		provides reliable storage for personal content	2
29	Offers Size Range	S, M, L, XL (range)		is a good fit for different body types	2
30A	Difference in color between wet and dry states	Binary		maintains its colour when wet	1
30B	Colour transfer due to bleeding			uses color pigments that stay in fabric	
31	Material type	Organic materials		is composed of environmentally friendly materials	1
32	Reflective Viewing distance	Feet		is reflective in the dark (is this still applicable?)	1

FEEDBACK

It would be great if you give me some feedback regarding the method, its procedure, assessment scales etc. Please feel free to write comments on the handout as well.

	strongly agree				strongly disagree
(Prior to the meeting) We understood what information is needed to conduct the method.	○	○	○	○	○
The procedure was easy to understand and to follow.	○	○	○	○	○
The tools (worksheet, handout with assessment scales) were appropriate.	○	○	○	○	○
I understood the outcomes that the process yielded.	○	○	○	○	○
The outcomes of the process correspond to what I believed before we conducted the method.	○	○	○	○	○
The results will help us with the project's progress.	○	○	○	○	○
The method imposes new actions we haven't previously considered.	○	○	○	○	○
The method would have helped me in previous and similar projects I've done.	○	○	○	○	○

OTHER COMMENTS AND SUGGESTIONS

9.4.6 Results of the Field Study

Team "Chalkboard Eraser", Apr 3rd 2007

Objective: Development of a chalkboard eraser that minimizes dust while removing chalk marks of all colors quickly and affordably

Team "Drinks and Hors d'Oeuvre without a Table", Apr 5th 2007

Objective: Development of a product that will allow user to hold both a plate and cup/glass in one hand easily and safely

Team "Combination of Toothbrush and Toothpaste", Apr 10th 2007

Objective: Development of an easy to use, portable, user friendly, effective, stand alone tooth cleaning tool for travelers that is as comfortable as traditional in-home solutions.

Team "Adjustable Insulation Jacket", Apr 18th 2007

Objective: Easy to use, durable, comfortable jacket with adjustable insulation levels for the outdoor environment

TEAM "CHALKBOARD ERASER"

OVERVIEW OF THE CONCEPTS

Review of Concept 1: Roller Eraser

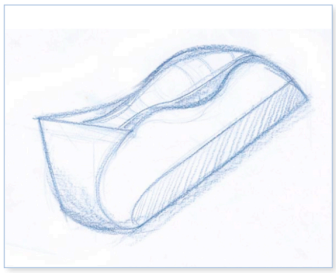
- It can be cleaned on the fly.

Review of Concept 2: Docking Station

- It can be used to clean erasers easily.

Review of Concept 3: Simple Eraser

- It's just a better eraser, using our new fabric.



CONCEPT "ROLLER ERASER"

Assessment Sheet

No.	Requirements Customer Needs	Specifications	Imp.	Accessibility (verbal description)	Accessibility Rating (A)	Feasibi (verbal
1	The eraser is affordable		5	We have a list of materials where the costs are listed. Additional information is needed regarding manufacturing etc.	3	Compa our "Si specifi more c
2	The eraser is unlikely to be stolen		4		0	
3	The eraser wipes board clean efficiently	Time required to erase the board to reach a satisfactory level of board cleanliness	5	First tests have been conducted. However more information is needed. Once we have a prototype we will have the information.	2	It is ha
4	The eraser fits on chalkboard tray		4		0	
5	The eraser captures dust	Amount of particulate matter (PM) within the immediate area of dust tray and/or hands	5	Once we have a prototype we will have the information.	3	We don captur sealing
6	The eraser has minimal maintenance requirements	# of times the erasing action can be repeated on the same board without outside cleaning intervention actions	4	More work to get infromation.	4	It is les solution the du
7	The eraser allows easy replacement of worn parts and does not "run out"		3		0	
8	The eraser is comfortable to use to erase 50m2 of board space		1		0	
9	The eraser only requires supplies found in a typical classroom during regular use		3		0	
10	The eraser enables all sizes of adult users to reach all corners of the board		2		0	
11	The eraser wipes board clean effectively	Gradient differentials between clean chalkboard and chalk colors	3	Once we have a prototype we will have the information.	2	It will b
12	~~The eraser allows for the blackboard surface to be used immediately after being cleaned~~		5	Enough information has been gathered.	1	All con require

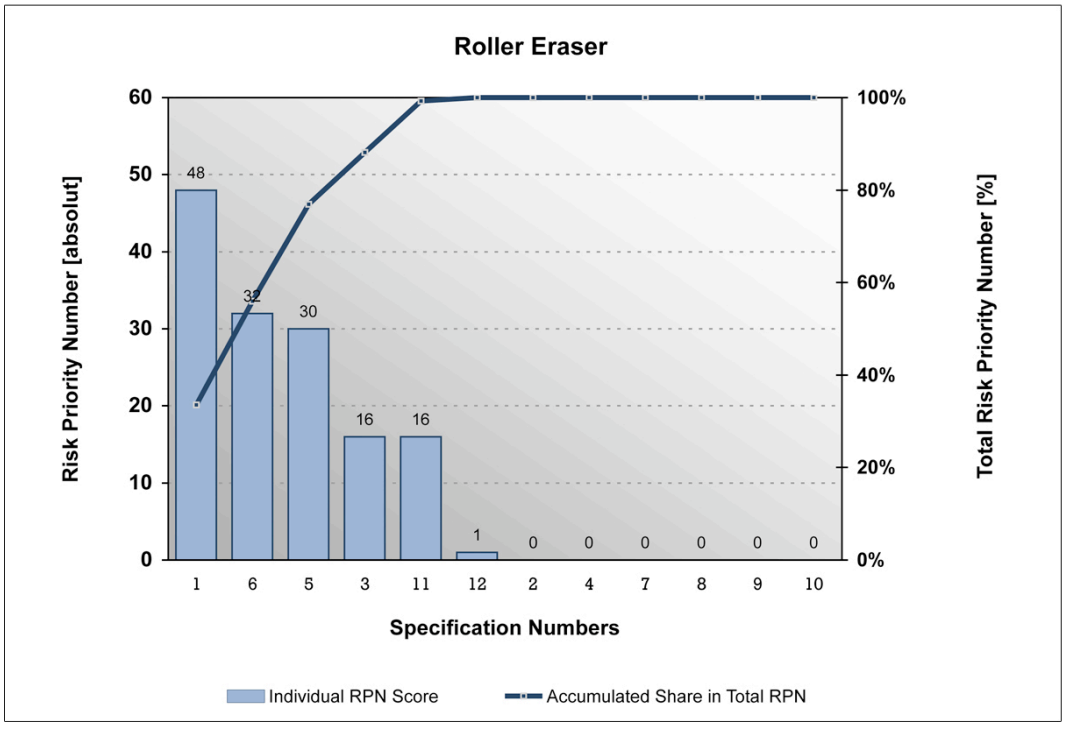
No.	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN
1	Compared to existing solutions or our "Simple Eraser", achieving this specification with this solution is more complicated.	8	Simple eraser as an alternative.	2	48
2		0		0	0
3	It is hard to built.	4	Simple eraser as an alternative.	2	16
4		0		0	0
5	We don't know how the concept will capture the dust. Especially the sealing will be challenging.	5	Simple eraser as an alternative. Different sealings exist.	2	30
6	It is less feasible than the "simple solution" due to the need to empty the dust.	4	Simple eraser as an alternative.	2	32
7		0		0	0
8		0		0	0
9		0		0	0
10		0		0	0
11	It will be hard to build.	4	Simple eraser as an alternative.	2	16
12	All considered concepts fulfill that requirement.	1	Alternatives are not necessary anymore. Thus, low rating.	1	1

Total RPN	143

Prioritized List

No.	Requirements	Accessibility Rating (A)	Feasibility Rating (F)	Contingency Rating (C)	RPN
1	The eraser is affordable	3	6	2	***36***
3	The eraser wipes board clean efficiently	5	3	2	***30***
6	The eraser has minimal maintenance requirements	4	3	2	***24***
11	The eraser wipes board clean effectively	2	4	2	***16***
5	The eraser captures dust	2	3	2	***12***
12	~~The eraser allows for the blackboard surface to be used immediately after being cleaned~~	1	1	1	***1***
2	The eraser is unlikely to be stolen				***0***
4	The eraser fits on chalkboard tray				***0***
7	The eraser allows easy replacement of worn parts and does not “run out”				***0***
8	The eraser is comfortable to use to erase 50m2 of board space				***0***
9	The eraser only requires supplies found in a typical classroom during regular use				***0***
10	The eraser enables all sizes of adult users to reach all corners of the board				***0***

Pareto Diagram



CONCEPT "DOCKING STATION"

Assessment Sheet

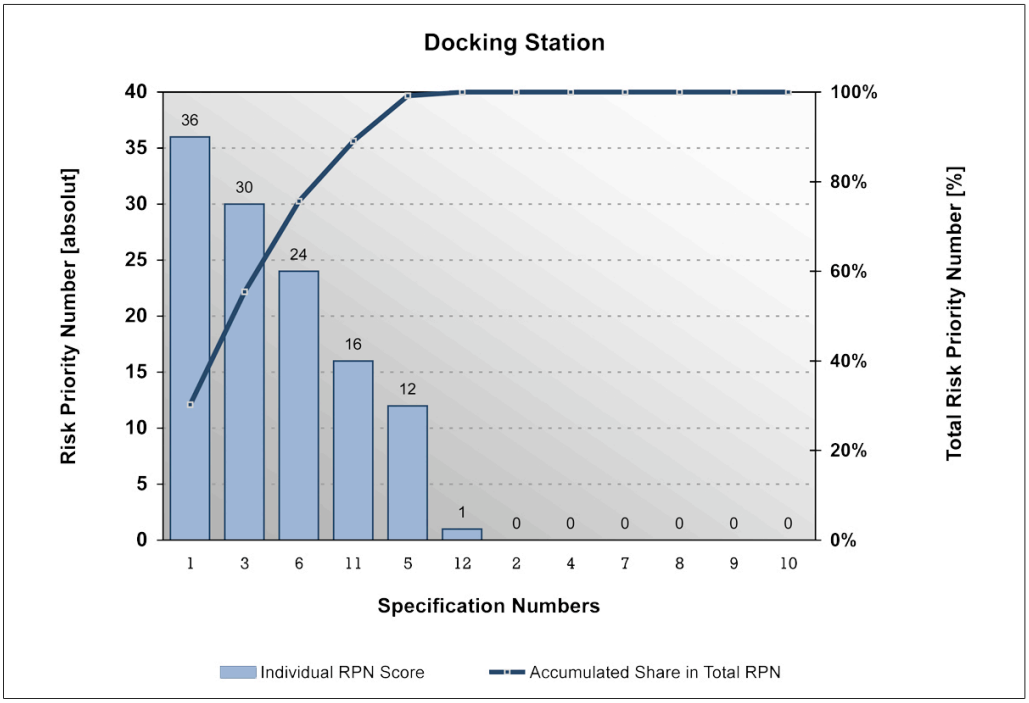
No.	Requirements Customer Needs	Specifications	Imp.	Accessibility (verbal description)	Accessi-bility Rating (A)	Fea (ver
1	The eraser is affordable		5	We have a list of materials where the costs are listed. Additional information is needed regarding manufacturing etc.	3	It w spe
2	The eraser is unlikely to be stolen		4			
3	The eraser wipes board clean efficiently	Time required to erase the board to reach a satisfactory level of board cleanliness	5		5	Inte the the
4	The eraser fits on chalkboard tray		4			
5	The eraser captures dust	Amount of particulate matter (PM) within the immediate area of dust tray and/or hands	5	Information can be gathered by testing with the prototype.	2	Con mo
6	The eraser has minimal maintenance requirements	# of times the erasing action can be repeated on the same board without outside cleaning intervention actions	4	More work to get infromation.	4	Pro Roll
7	The eraser allows easy replacement of worn parts and does not "run out"		3			
8	The eraser is comfortable to use to erase 50m2 of board space		1			
9	The eraser only requires supplies found in a typical classroom during regular use		3			
10	The eraser enables all sizes of adult users to reach all corners of the board		2			
11	The eraser wipes board clean effectively	Gradient differentials between clean chalkboard and chalk colors	3	Once we have a prototype we will have the information.	2	
12	~~The eraser allows for the blackboard surface to be used immediately after being cleaned~~		5	Enough information has been gathered.	1	All that

No.	Feasibility (verbal description)	Feasibi-lity Rating (F)	Contingency (verbal description)	Conting-ency Rating (C)	RPN
1	It will be hard to achieve this specification with this concept.	6	We know some alternatives, especially the simple eraser.	2	36
2					0
3	Interpretation: The eraser wipes the board efficiently after using the docking station.	3		2	30
4					0
5	Compared to concept 1, it is more feasible.	3	Simple eraser as an alternative.	2	12
6	Probably more feasible than the Roller Eraser.	3	Simple eraser as an alternative.	2	24
7					0
8					0
9					0
10					0
11		4		2	16
12	All considered concepts fulfill that requirement.	1	Alternatives are not necessary anymore. Thus, low rating.	1	1

Prioritized List

No.	Requirements	Accessibility Rating (A)	Feasibility Rating (F)	Contingency Rating (C)	RPN
1	The eraser is affordable	3	6	2	***36***
3	The eraser wipes board clean efficiently	5	3	2	***30***
6	The eraser has minimal maintenance requirements	4	3	2	***24***
11	The eraser wipes board clean effectively	2	4	2	***16***
5	The eraser captures dust	2	3	2	***12***
12	The eraser allows for the blackboard surface to be used immediately after being cleaned	1	1	1	***1***
2	The eraser is unlikely to be stolen				***0***
4	The eraser fits on chalkboard tray				***0***
7	The eraser allows easy replacement of worn parts and does not “run out”				***0***
8	The eraser is comfortable to use to erase 50m2 of board space				***0***
9	The eraser only requires supplies found in a typical classroom during regular use				***0***
10	The eraser enables all sizes of adult users to reach all corners of the board				***0***

Pareto Diagram



CONCEPT "SIMPLE ERASER"

Assessment Sheet

No.	Requirements Customer Needs	Specifications	Imp.	Accessibility (verbal description)	Accessibility Rating (A)
1	The eraser is affordable		5	We have a list of materials where the costs are listed. Additional information is needed regarding manufacturing etc.	3
2	The eraser is unlikely to be stolen		4		0
3	The eraser wipes board clean efficiently	Time required to erase the board to reach a satisfactory level of board cleanliness	5	First tests have been conducted. However more information is needed. Once we have a prototype we will have the information.	2
4	The eraser fits on chalkboard tray		4		0
5	The eraser captures dust	Amount of particulate matter (PM) within the immediate area of dust tray and/or hands	5	Once we have a prototype we will have the information.	3
6	The eraser has minimal maintenance requirements	# of times the erasing action can be repeated on the same board without outside cleaning intervention actions	4	More work to get infromation.	4
7	The eraser allows easy replacement of worn parts and does not "run out"		3		0
8	The eraser is comfortable to use to erase 50m2 of board space		1		0
9	The eraser only requires supplies found in a typical classroom during regular use		3		0
10	The eraser enables all sizes of adult users to reach all corners of the board		2		0
11	The eraser wipes board clean effectively	Gradient differentials between clean chalkboard and chalk colors	3	Once we have a prototype we will have the information.	2
12	~~The eraser allows for the blackboard surface to be used immediately after being cleaned~~		5	Enough information has been gathered.	1

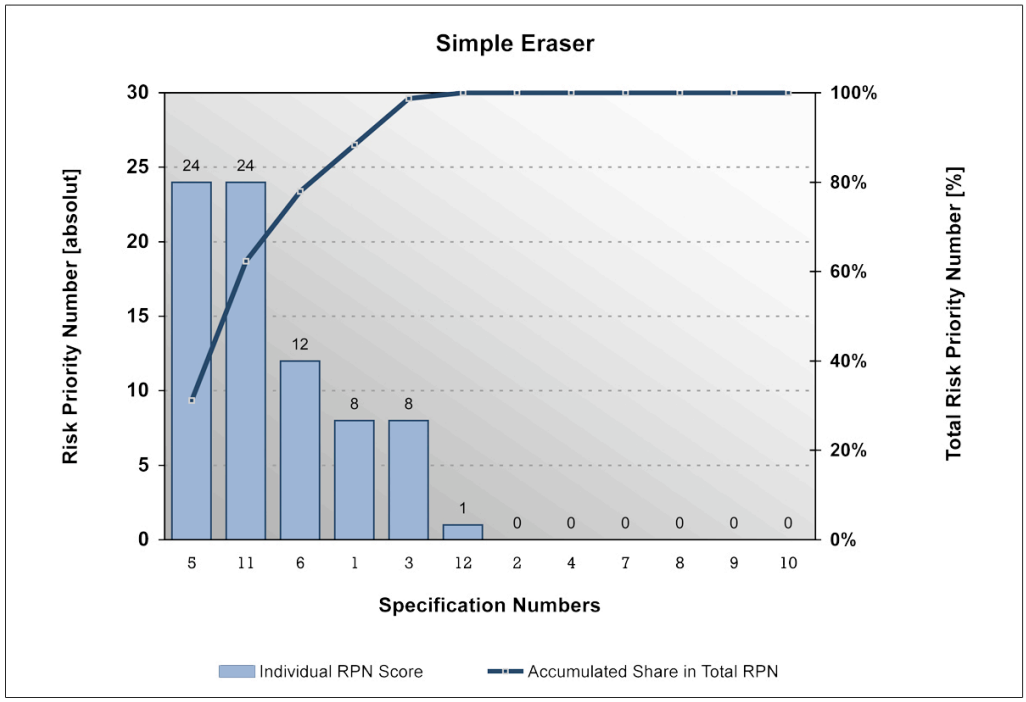
No.	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN
1	Compared to existing solutions or our "Simple Eraser", achieving this specification with this solution is more complicated.	8	Simple eraser as an alternative.	2	48
2		0		0	0
3	It is hard to built.	4	Simple eraser as an alternative.	2	16
4		0		0	0
5	We don't know how the concept will capture the dust. Especially the sealing will be challenging.	5	Simple eraser as an alternative. Different sealings exist.	2	30
6	It is less feasible than the "simple solution" due to the need to empty the dust.	4	Simple eraser as an alternative.	2	32
7		0		0	0
8		0		0	0
9		0		0	0
10		0		0	0
11	It will be hard to build.	4	Simple eraser as an alternative.	2	16
12	All considered concepts fulfill that requirement.	1	Alternatives are not necessary anymore. Thus, low rating.	1	1

Total RPN	143

Prioritized List

No.	Requirements	Accessibility Rating (A)	Feasibility Rating (F)	Contingency Rating (C)	RPN
5	The eraser captures dust	2	6	2	***24***
11	The eraser wipes board clean effectively	2	6	2	***24***
6	The eraser has minimal maintenance requirements	3	2	2	***12***
1	The eraser is affordable	2	2	2	***8***
3	The eraser wipes board clean efficiently	2	2	2	***8***
12	The eraser allows for the blackboard surface to be used immediately after being cleaned	1	1	1	***1***
2	The eraser is unlikely to be stolen				***0***
4	The eraser fits on chalkboard tray				***0***
7	The eraser allows easy replacement of worn parts and does not “run out”				***0***
8	The eraser is comfortable to use to erase 50m2 of board space				***0***
9	The eraser only requires supplies found in a typical classroom during regular use				***0***
10	The eraser enables all sizes of adult users to reach all corners of the board				***0***

Pareto Diagram



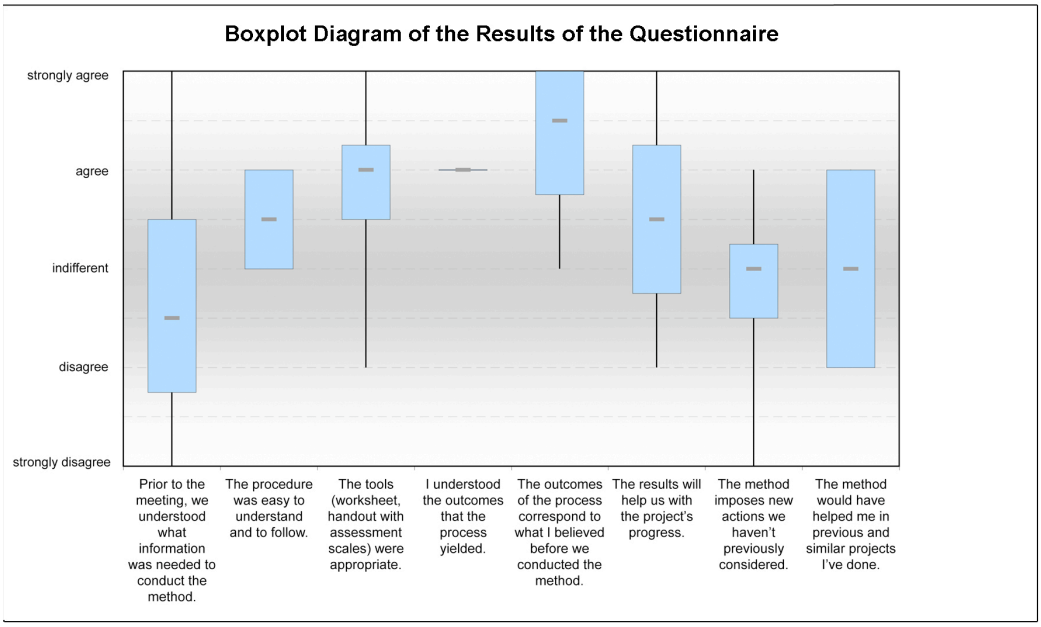
FEEDBACK TEAM "CHALKBOARD ERASER"

	strongly disagree				strongly agree	
Prior to the meeting, we understood what information was needed to conduct the method.	1	0	1	1	1	Σ 4
The procedure was easy to understand and to follow.	0	2	2	0	0	Σ 4
The tools (worksheet, handout with assessment scales) were appropriate.	1	2	0	1	0	Σ 4
I understood the outcomes that the process yielded.	0	4	0	0	0	Σ 4
The outcomes of the process correspond to what I believed before we conducted the method.	2	1	1	0	0	Σ 4
The results will help us with the project's progress.	1	1	1	1	0	Σ 4
The method imposes new actions we haven't previously considers.	0	1	2	0	1	Σ 4
The method would have helped me in previous and similar projects I've done.	0	2	0	2	0	Σ 4

Other Comments

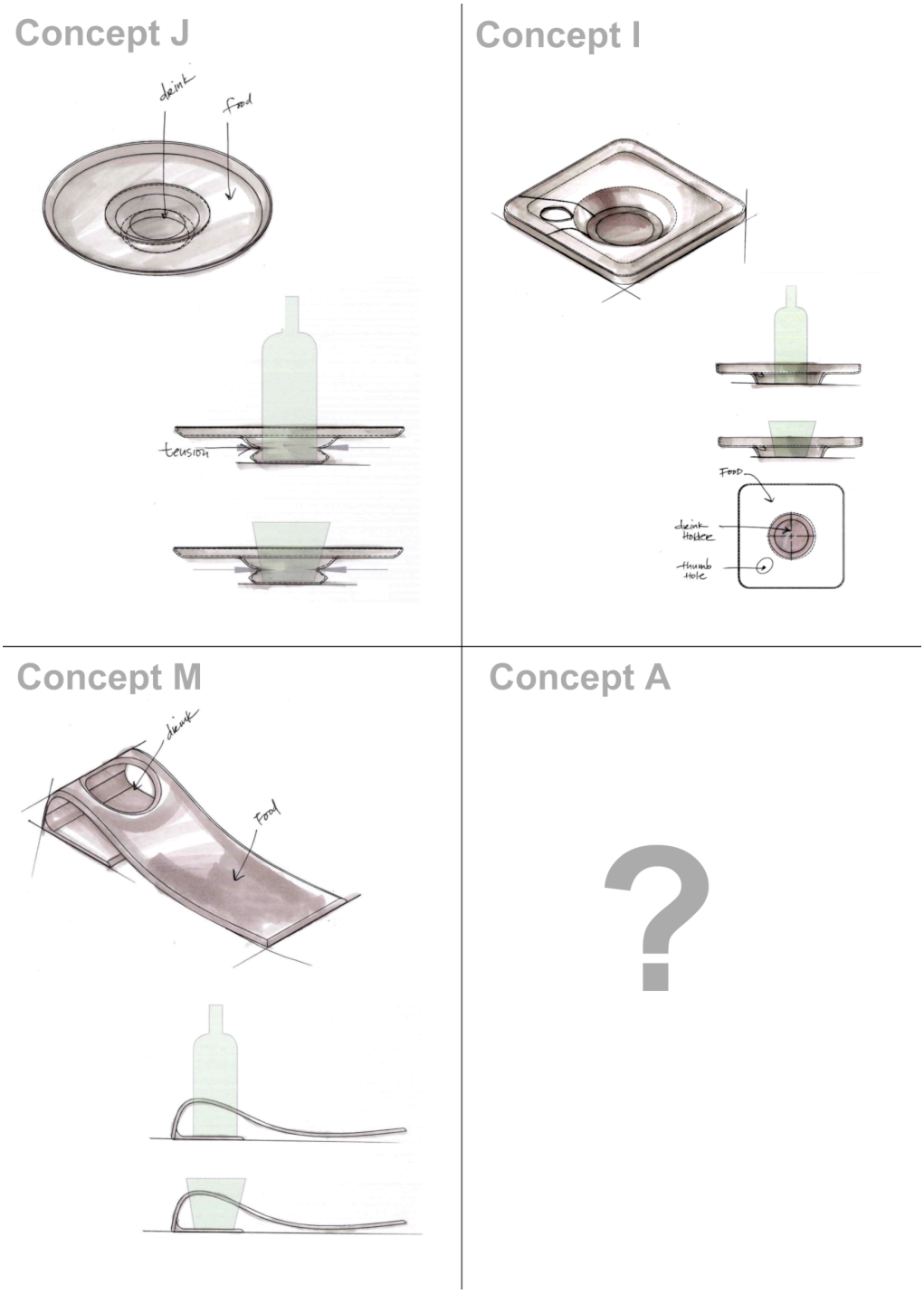
Maybe be more helpful farther down the process

Pretty slow, I'm not sure I learned much more info from this, very simply proceed, so easier to wrap my mind about it



Team “Drinks and Hors d’Oeuvre without a Table”

OVERVIEW OF THE CONCEPTS



No picture of Concept A was provided. According to the team, it looked similar to Concept J and had some minor difference. Thus, Concept A was rather seen as a variant than a concept on its own.

GENERAL ASSESSMENT SHEET

No.	Requirements Specifications...	Concepts	Accessibility (verbal description)	Accessibility Rating (A)	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN
1	Weight unit supports	J	Much information has been collected form existing products, however additional information needs to be collected.	2		3	The structure of this concept can be compounded, another material chosen...	2	**12**
		I		2		3	see Concept J	2	**12**
		M		2	Due to the length of this concept it is more challenging to achieve this specification (momentum arm).	5	Due to its dimensions, it's slightly more challenging to strenghten the structure of this conecept (make it shorter, different structure). The alternatives would be less attractive.	3	**30**
		A		2		3	see Concept J	2	**12**
2	% of food unit can accommodate	J							**0**
		I							**0**
		M							**0**
		A							**0**
3	Weight of unit	J							**0**
		I							**0**
		M							**0**
		A							**0**
4	User's aesthetic rating	J	We are very confident. We just have to ask enough people.	2	The concept is more functionality driven.	5	It will be harder to change the design, because the "hole" in the middle is kind of "fixed".	8	**80**
		I		2	see J	5		8	**80**
		M		2	This concept is more aesthetics-driven.	2	With this concept, there is much more room to play around.	4	**16**
		A		2	see J	5		8	**80**
5	Number of compatible cups (regarding the size)	J	We do testing after this meeting and get the information.	2	The tension might not accomodate all sizes.	4	You can design a two-level tension, expand it, vary the diameter...	4	**32**
		I	see J	2	Concept I accomodates a lot of different sizes.	2	The diameter of the hole can be varied easily.	2	**8**
		M	Gaining information for this concept is a little bit more difficult than for the others.	3	see I	2	see I	2	**12**
		A	see J	2		3	see I	2	**12**
6	~~Number of compatible plates~~	J							**0**
		I							**0**
		M							**0**
		A							**0**
7	Stabilitiy of the cup while walking	J	We can measure that specification by conducting tests. The difficulty is to get a representative number of test persons and design a reliable test.	4	This concept is probably the most stable one.	2	We know of a lot alternatives: You can increase the tension, add holder, You can even design different sizes.	1	**8**
		I		4		5	We know of a lot alternatives. However, they are slightly more challenging for this concept than for Concept J.	2	**40**
		M		4	The feasability of M is a little bit harder to achieve than J because of the diagonal support.	3	We know of some less attractive alternatives. The tension cannot be increased so easily.	4	**48**
		A		4		6	We would have to adjust the design.	4	**96**
8	Speed of walking with unit	J							**0**
		I							**0**
		M							**0**
		A							**0**
9	Ease of remove the cup from the plate	J		3	It is challenging to achieve this due to the concept of the tension.	4	If it is to hard to remove the cup, we'll make the hole bigger and need to adjust the tension.	3	**36**
		I		3		2	It is just a meter of dimensions, we would have to adjust the current dimensions.	2	**12**
		M		3		2	see I	2	**12**
		A		3		2	see I	2	**12**
10	Volume to store 100 units	J							**0**
		I							**0**
		M							**0**
		A							**0**
11	Dimension of single unit	J							**0**
		I							**0**
		M							**0**
		A							**0**
12	Unit manufacturing costs	J	For all concepts, additonal information has to be collected. It is not know if that can be achieved easily within the remaining time.	5	Due to the necessary tension, the production tolerances might be minor than for other concepts.	3	Alternatives are less attractive.	4	**60**
		I		5		2		4	**40**
		M		5		5	We are already designing an alternative that can be made out of one sheet and should achieve target costs in a better way.	1	**25**
		A		5		3		4	**60**

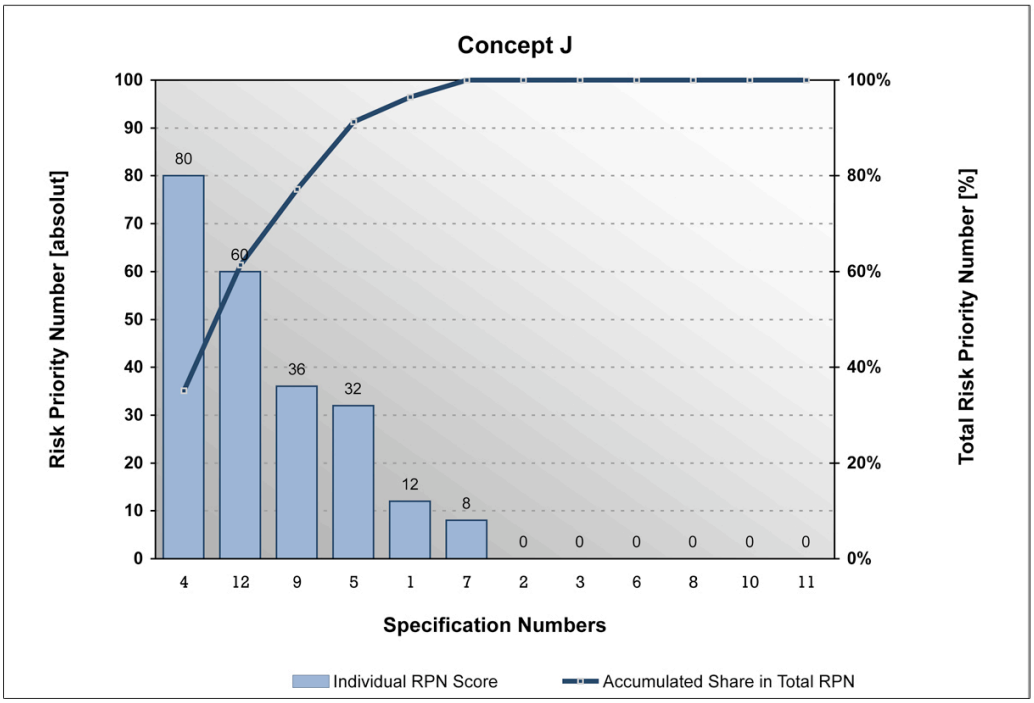
Total RPN for Concept I	**228**
Total RPN for Concept J	**192**
Total RPN for Concept M	**143**
Total RPN for Concept A	**272**

CONCEPT J

Prioritized List

No.	Requirements Specifications...	... derived from the Customer Need(s)	Accessibility Rating (A)	Feasibility Rating (F)	Contingency Rating (C)	RPN
4	User's aesthetic rating	Aesthetically pleasing	2	5	8	***80***
12	Unit manufacturing costs	Affordable	5	3	4	***60***
9	Ease of remove the cup from the plate	This specification was introduced during the meeting. It is derived from a	3	4	3	***36***
5	Number of compatible cups (regarding the size)	Accommodates different diameter of cups, bottles, and cans (formerly:	2	4	4	***32***
1	Weight unit supports	Stable when in use, Portable	2	3	2	***12***
7	Stabilitiy of the cup while walking	Portable	4	2	1	***8***
2	% of food unit can accommodate	Accommodates foods and drinks served at functions	0	0	0	***0***
3	Weight of unit	Light-weight Portable	0	0	0	***0***
6	Number of compatible plates	Accommodates different diameter glasses and plates	0	0	0	***0***
8	Speed of walking with unit	Stable when in use Portable	0	0	0	***0***
10	Volume to store 100 units	Easy to store/stack	0	0	0	***0***
11	Dimension of single unit	Portable Easy to store/stack	0	0	0	***0***

Pareto Diagram

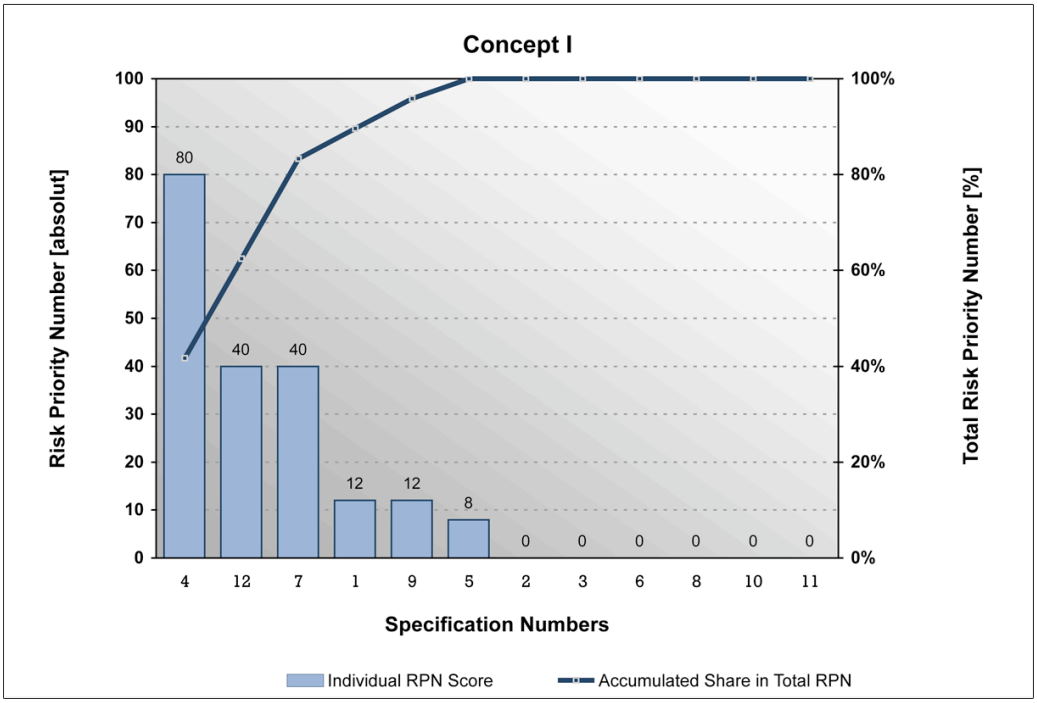


CONCEPT I

Prioritized List

No.	Requirements Specifications...	... derived from the Customer Need(s)	Accessi-bility Rating (A)	Feasibi-lity Rating (F)	Conting-ency Rating (C)	RPN
4	User's aesthetic rating	Aesthetically pleasing	2	5	8	***80***
12	Unit manufacturing costs	Affordable	5	2	4	***40***
7	Stabilitiy of the cup while walking	Portable	4	5	2	***40***
1	Weight unit supports	Stable when in use, Portable	2	3	2	***12***
9	Ease of remove the cup from the plate	This specification was introduced during the meeting. It is derived from a discussion	3	2	2	***12***
5	Number of compatible cups (regarding the size)	Accommodates different diameter of cups, bottles, and cans (formerly: glasses)	2	2	2	***8***
2	% of food unit can accommodate	Accommodates foods and drinks served at functions	0	0	0	***0***
3	Weight of unit	Light-weight Portable	0	0	0	***0***
6	Number of compatible plates	Accommodates different diameter glasses and plates	0	0	0	***0***
8	Speed of walking with unit	Stable when in use Portable	0	0	0	***0***
10	Volume to store 100 units	Easy to store/stack	0	0	0	***0***
11	Dimension of single unit	Portable Easy to store/stack	0	0	0	***0***

Pareto Diagram

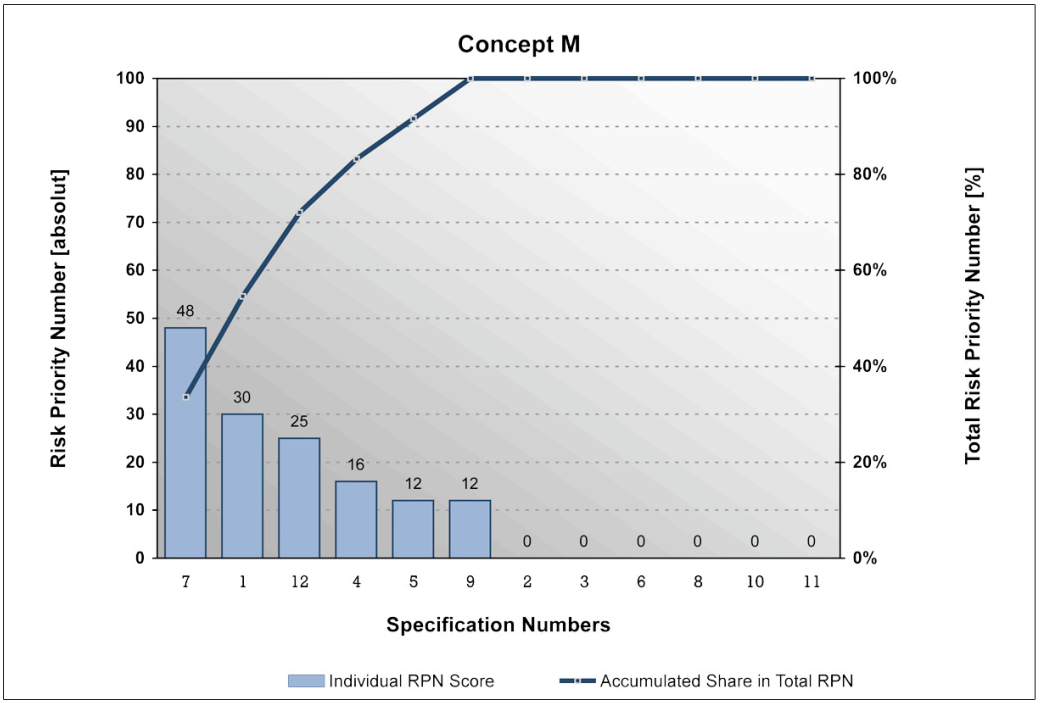


CONCEPT M

Prioritized List

No.	Requirements Specifications...	... derived from the Customer Need(s)	Accessi-bility Rating (A)	Feasibi-lity Rating (F)	Conting-ency Rating (C)	RPN
7	Stabilitiy of the cup while walking	Portable	4	3	4	***48***
1	Weight unit supports	Stable when in use, Portable	2	5	3	***30***
12	Unit manufacturing costs	Affordable	5	5	1	***25***
4	User's aesthetic rating	Aesthetically pleasing	2	2	4	***16***
5	Number of compatible cups (regarding the size)	Accommodates different diameter of cups, bottles, and cans (formerly:	3	2	2	***12***
9	Ease of remove the cup from the plate	This specification was introduced during the meeting. It is derived from a	3	2	2	***12***
2	% of food unit can accommodate	Accommodates foods and drinks served at functions	0	0	0	***0***
3	Weight of unit	Light-weight Portable	0	0	0	***0***
6	Number of compatible plates	Accommodates different diameter glasses and plates	0	0	0	***0***
8	Speed of walking with unit	Stable when in use Portable	0	0	0	***0***
10	Volume to store 100 units	Easy to store/stack	0	0	0	***0***
11	Dimension of single unit	Portable Easy to store/stack	0	0	0	***0***

Pareto Diagram

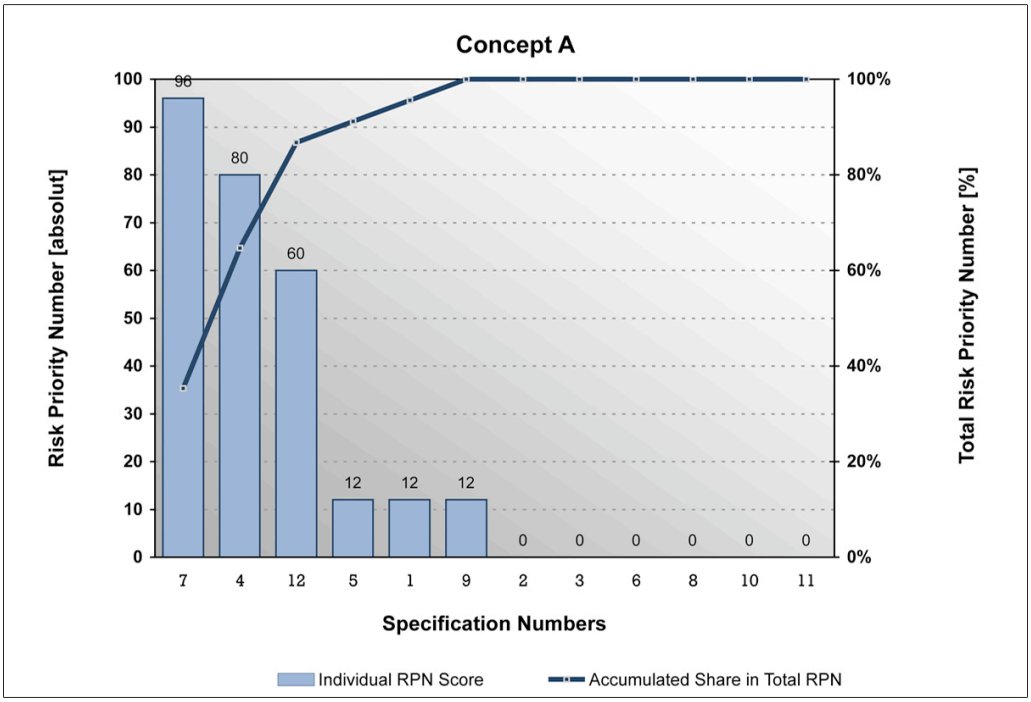


CONCEPT A

Prioritized List

No.	Requirements Specifications...	... derived from the Customer Need(s)	Accessi-bility Rating (A)	Feasibility Rating (F)	Conting-ency Rating (C)	RPN
7	Stabilitiy of the cup while walking	Portable	4	6	4	***96***
4	User's aesthetic rating	Aesthetically pleasing	2	5	8	***80***
12	Unit manufacturing costs	Affordable	5	3	4	***60***
5	Number of compatible cups (regarding the size)	Accommodates different diameter of cups, bottles, and cans (formerly:	2	3	2	***12***
1	Weight unit supports	Stable when in use, Portable	2	3	2	***12***
9	Ease of remove the cup from the plate	This specification was introduced during the meeting. It is derived from a	3	2	2	***12***
2	% of food unit can accommodate	Accommodates foods and drinks served at functions	0	0	0	***0***
3	Weight of unit	Light-weight Portable	0	0	0	***0***
6	~~Number of compatible plates~~	~~Accommodates different diameter glasses and plates~~	0	0	0	***0***
8	Speed of walking with unit	Stable when in use Portable	0	0	0	***0***
10	Volume to store 100 units	Easy to store/stack	0	0	0	***0***
11	Dimension of single unit	Portable Easy to store/stack	0	0	0	***0***

Pareto Diagram

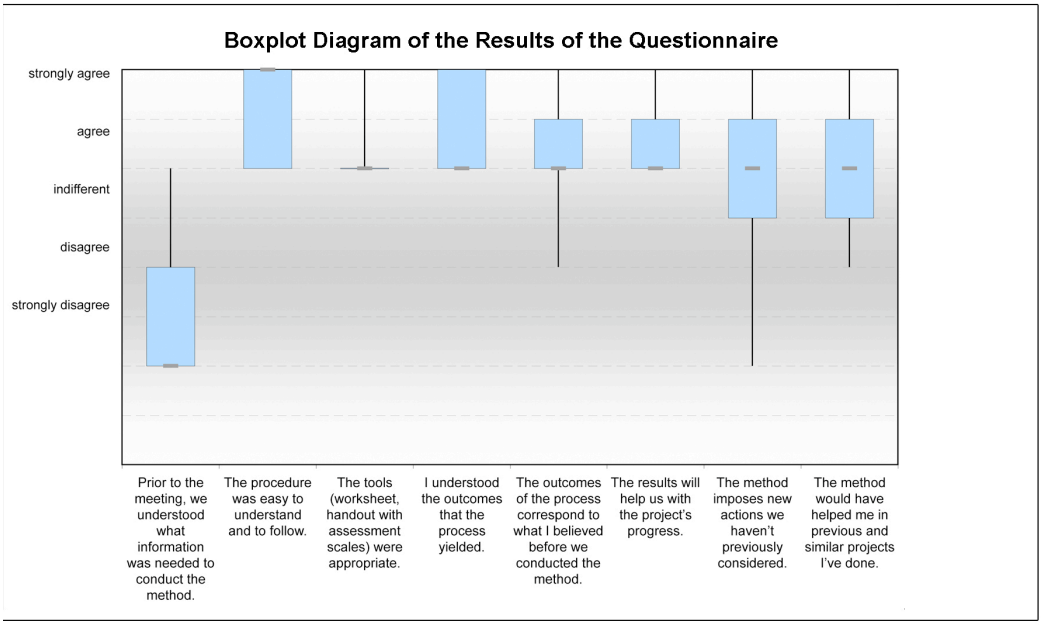


FEEDBACK TEAM "'DRINKS AND HORS D'OEUVRE WITHOUT A TABLE"

	strongly disagree				strongly agree	
Prior to the meeting, we understood what information was needed to conduct the method.	0	1	2	4	0	∑ 7
The procedure was easy to understand and to follow.	4	3	0	0	0	∑ 7
The tools (worksheet, handout with assessment scales) were appropriate.	1	6	0	0	0	∑ 7
I understood the outcomes that the process yielded.	3	4	0	0	0	∑ 7
The outcomes of the process correspond to what I believed before we conducted the method.	2	4	1	0	0	∑ 7
The results will help us with the project's progress.	2	5	0	0	0	∑ 7
The method imposes new actions we haven't previously considers.	2	3	1	1	0	∑ 7
The method would have helped me in previous and similar projects I've done.	2	3	2	0	0	∑ 7

Other Comments

It was good to go over the process, but perhaps it would have been more efficient if we could have split the team up to rank different attributes.



Team “Combination of Toothbrush and Toothpaste”

OVERVIEW OF THE CONCEPT

Assessment Sheet

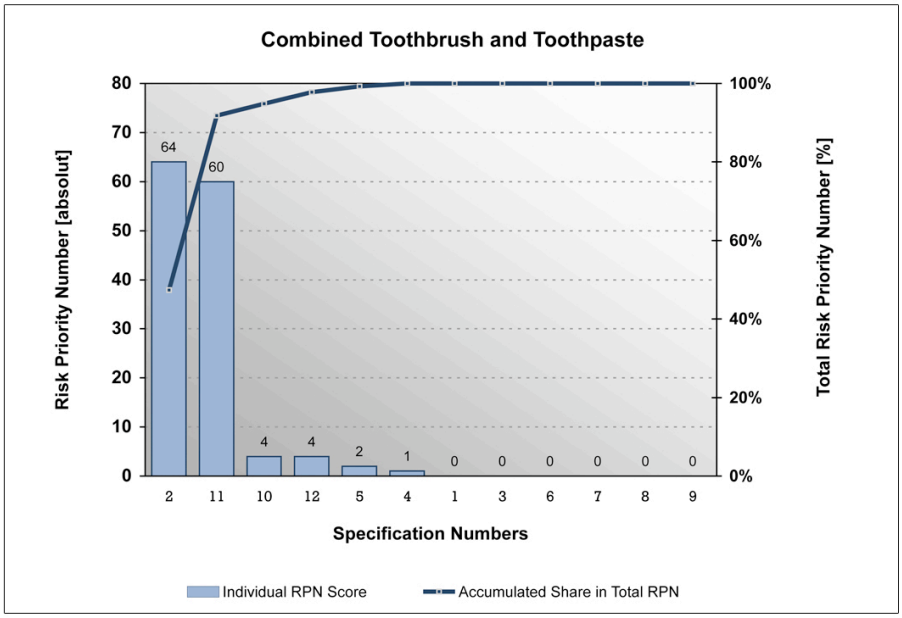
No.	Specifications Metric	Value	Unit	Accessibility (verbal description)	Accessibility Rating (A)	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN
~~1~~	~~Visible Particulates of Food Left in Bristles~~	~~<1~~	~~Number~~							0
2	Presence of Harmful Bacterium	*Better than existing (cover) solutions.*	PPM *(over time)*	We may set up an experiment (take a swab, compare it to existing solutions). It will certainly be challenging to get the information.	8	We think it is likely to meet the specification because it's similar to exisitng solutions.	2	There are some alternatives (add mouthwash, antibacterical coating, bacteria-killing toothpaste, lower the recommended number of uses). Thus, they are less attractive.	4	64
3	~~Transparent Brush Head (lower occurrence of bacterial growth)~~	~~>50%~~	~~Light Penetration~~	*We eliminate that specification, because people are using their own toothbrush.*						0
4	Liquid / Gel Volume	<3	Oz	Enough information has been collected.	1	It is assured that this concept will meet the specification.	1	We would simply change the size (dimensions).	1	1
5	Overall Size (if includes liquid/gel)	Fits 1qt Bag	Inches	Enough information has been collected.	1	It fits with other things in a bag.	1	There are a couple of alternatives: take the toothbrush out of the bag, change the design (shape), change the repository of the toothpaste	2	2
6	~~Sharp Object Length~~	~~<4~~	~~Inches~~							0
~~7~~	~~On Prohibited Object List~~	~~No~~	~~Binary~~							0
8	~~Turesky Modified Quigley & Hein Plaque Index~~	~~Low (0 or 1)~~	~~Score~~							0
9	~~Turesky Modified Quigley & Hein Plaque Index~~	~~Statistically Significant to 15% Over Placebo~~	~~Score~~							0
10	Number of Pre- and Post-brushing Steps	<~9	Number	We haven't estimated that for the current prototype, but that information is available and easy to get.	2	If we combine the both parts, it will be probably even less steps.	1	We've discussed a lot of alternatives. (We even have ideas of combining of floss to the clip)	2	4
11	Cumbersome	No	Subjective	We have a good idea which information we need and have a sense of how to get it. However, it's still a bit uncertain if we can get	5	We believe it is feasible, however it is not assured.	4	We know some alternatives. We don't knowhow attractive they are.	3	60
12	Number of Capabilites	>2	Number	We haven't estimated that for the current prototype, but that information is available and easy to get.	2	Based on our knowledge, we think that is absolutely feasible.	1	Even if that concept didn't meet the spec, we could easily add features.	2	4

Total RPN	135

Prioritized List

No.	Specifications Metric	Value	Unit	Accessibility Rating (A)	Feasibility Rating (F)	Contingency Rating (C)	RPN
2	Presence of Harmful Bacterium	Better than existing (cover) solutions.	PPM (over time)	8	2	4	***64***
11	Cumbersome	No	Subjective	5	4	3	***60***
10	Number of Pre- and Post-brushing Steps	<~9	Number	2	1	2	***4***
12	Number of Capabilites	>2	Number	2	1	2	***4***
5	Overall Size (if includes liquid/gel)	Fits 1qt Bag	Inches	1	1	2	***2***
4	Liquid / Gel Volume	<3	Oz	1	1	1	***1***
~~1~~	~~Visible Particulates of Food Left in Bristles~~	~~<1~~	~~Number~~				***0***
3	~~Transparent Brush Head (lower occurrence of bacterial~~	~~>50%~~	~~Light Penetratio~~				***0***
6	~~Sharp Object Length~~	~~<4~~	~~Inches~~				***0***
~~7~~	~~On Prohibited Object List~~	~~No~~	~~Binary~~				***0***
8	~~Turesky Modified Quigley & Hein Plaque Index~~	~~Low (0 or 1)~~	~~Score~~				***0***
9	~~Turesky Modified Quigley & Hein Plaque Index~~	~~Statistically Significant to 15% over Placebo~~	~~Score~~				***0***

Pareto Diagram

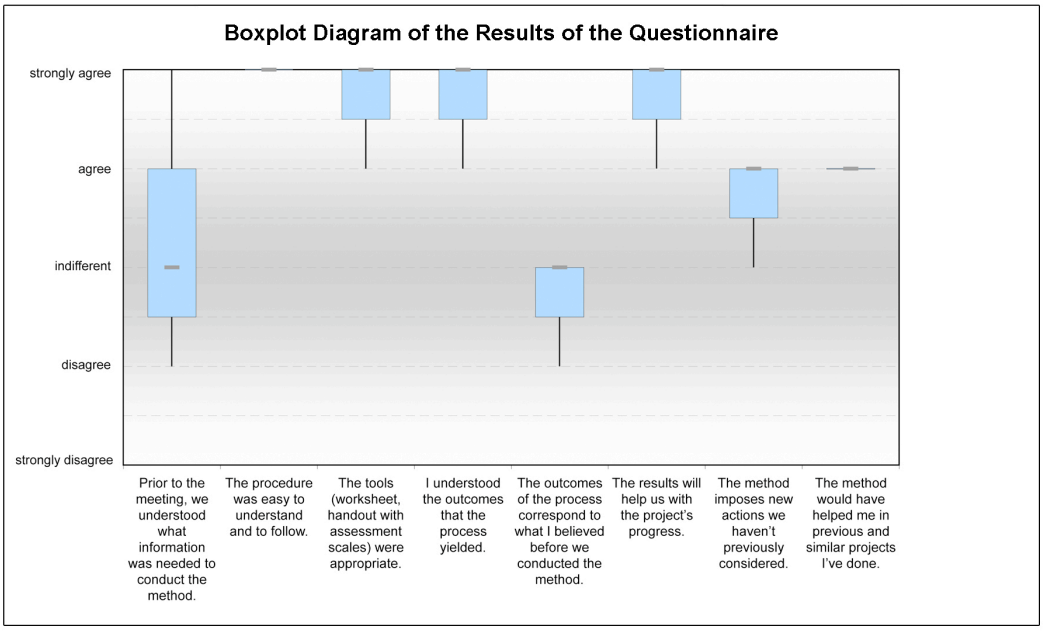


Recommended Actions

No.	Specifications Metric	RPN	Recommended action(s)	Responsibility	Completion Date
2	Presence of Harmful Bacterium	*64*	Check if there is information online (existing solution) so that we can assess the feasibility Check if we can setup experiments	Will be discussed in one of the next team meetings.	Will be discussed in one of the next team meetings.
11	Cumbersome	*60*	We should focus on the physical design: size of product, how well it atttaches to the brush, how easy to dispense paste. Furthermore, we will ask as many people as we can find about the prototypes we'll build (immediate testing while building the final prototype).	Will be discussed in one of the next team meetings.	Will be discussed in one of the next team meetings.
10	Number of Pre- and Post-brushing Steps	*4*			
12	Number of Capabilites	*4*			
5	Overall Size (if includes liquid/gel)	*2*			
4	Liquid / Gel Volume	*1*			
1	~~Visible Particulates of Food Left in Bristles~~	*0*			
3	~~Transparent Brush Head (lower occurrence of bacterial~~	*0*			
6	~~Sharp Object Length~~	*0*			
7	~~On Prohibited Object List~~	*0*			
8	~~Turesky Modified Quigley & Hein Plaque Index~~	*0*			
9	~~Turesky Modified Quigley & Hein Plaque Index~~	*0*			

FEEDBACK TEAM "COMBINATION OF TOOTHBRUSH AND TOOTHPASTE"

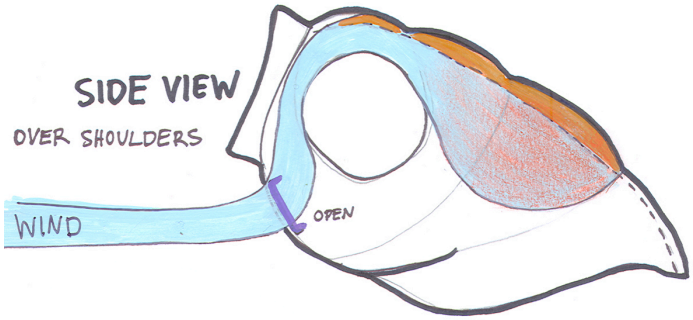
	strongly disagree				strongly agree	
Prior to the meeting, we understood what information was needed to conduct the method.	1	0	1	1	0	∑ 3
The procedure was easy to understand and to follow.	3	0	0	0	0	∑ 3
The tools (worksheet, handout with assessment scales) were appropriate.	2	1	0	0	0	∑ 3
I understood the outcomes that the process yielded.	2	1	0	0	0	∑ 3
The outcomes of the process correspond to what I believed before we conducted the method.	0	0	2	1	0	∑ 3
The results will help us with the project's progress.	2	1	0	0	0	∑ 3
The method imposes new actions we haven't previously considers.	0	2	1	0	0	∑ 3
The method would have helped me in previous and similar projects I've done.	0	3	0	0	0	∑ 3

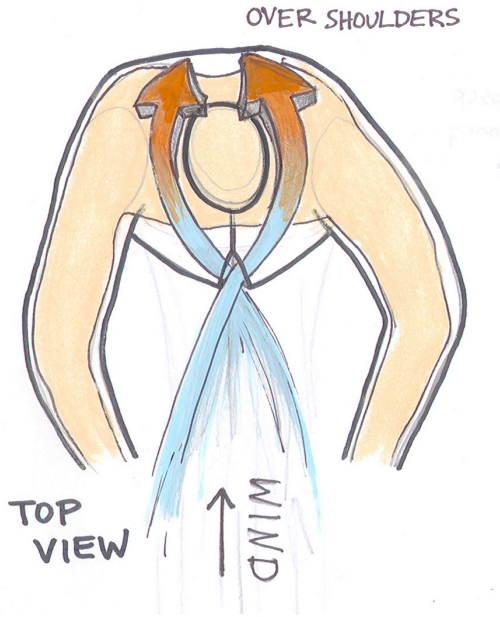


Team “Adjustable Insulation Jacket”

OVERVIEW OF THE FINAL DRAFT

For the analysis, no picture was provided by the team. In order to establish a better understanding, the following figure shows the final draft of the Adjustable Insulation Jacket.





Assessment Sheet

No.	Specifications Metric	Unit	... Derived from the Customer Need	Accessibility (verbal description)	Accessi-bility Rating (A)
1	Insulation level (Thermal Resistance range) is adjustable	R-value ((square meters x °C)/watts)	adjusts heat loss from the body	We've already build great models and collected enough information.	1
3	Total Mass	Kilogram	is light-weight	We know how to calculate the mass but we still need some more information (This is dependend on the material choice)	2
6	Air flow per square meter per time	Meter3/meter 2/time	allows ventilation to sweat prone areas of body	We have some rough models and we can make some rough approximations. Additional information needs to be gathered.	3
11	Unit Manufacturing Cost	US $	is affordable for consumer	We have a good idea where to get the information. There is a large variability in the manufacturing costs. It is depending on a lot of variables we don't know yet.	5
12	Time required for adjusting insulation level	Seconds	is quick to use	We've collected enough data.	1
19	Style (subjective)	Binary	is stylish and fashionable (is this still applicable?)	It is hard to get the information whether the concept is stylish and faishonable. There are a lot of different opinions. Time might be a restricting factor to collect the information as well..	8
20	***Wearing volume*** (former ~~Packing volume~~)	Meter3	~~is stored easily~~ ***wearing volume***	We can get the information by asking people. It may be difficult to find out what the customer really wants within the remaining time.	3
21	Wind permeability of material (Fraser Air Permeability Test)	CFM	is wind-resistant/ wind-proof	We can take material data, but we might need some more information.	2
26	Water vapour transmission rate	Grams/square meter per 24 hours	is breathable (THIS SHOULD BE HIGHER!!!) ***for the whole jacket (not just material)***	We need to get some more information in advance and run some experiments while building the final prototype. It will be challenge to get the necessary information on time.	4
34					
35					

Assessment Sheet (2)

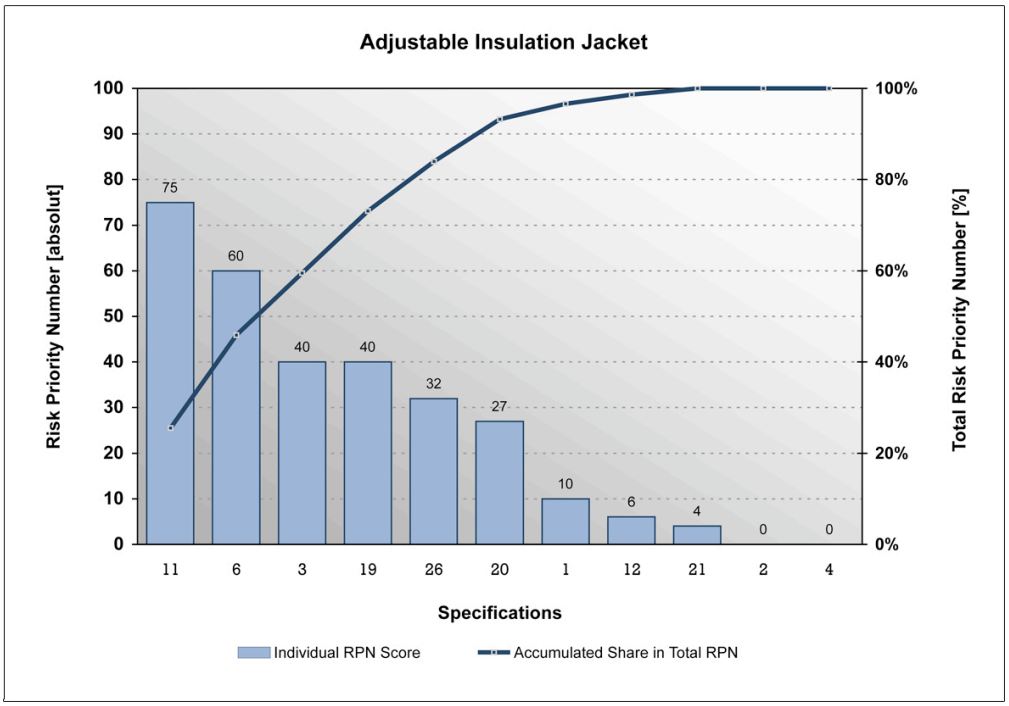
No.	Feasibility (verbal description)	Feasibility Rating (F)	Contingency (verbal description)	Contingency Rating (C)	RPN
1	We think it is highly feasible.	2	We can adjust materials so that they are less breathable (foam, plastics), we can adjust the thickness... However the alternatives are less attractive.	5	***10***
3	The benchmark ranges from the bycling jacket to heavier jackets. While we are pretty sure that the concept has less weight than those jackets, the weight of the bicycling jacket may be hard to reach.	4	There is not much we can do. We can change the material or design, but that's certainly less attractive.	5	***40***
6	We believe that it is possible to achieve this specifications.	5	We can change the design (gaps, ...). However, trade offs have to be made (aesthetics, comfort, ...) and are less attractive.	4	***60***
11	The benchmark ranges from 200 to 300$ for adjustable jackets. We think it is likely to meet that specification.	3	There are some alternatives. We can change the material (e.g. switch to Nylon). We are not sure about the production amount, about manufacturing costs in different countries.	5	***75***
12	It is very likely to meet this specification.	2	We have some alternatives but they may not be as good.	3	***6***
19	We believe that it is possible to achieve this specification.	5	There is all sort of alternatives: We can change colors, logos, etc.	1	***40***
20	It is pretty feasible. The one concern is that the jacket is too bulky in certain locations.	3	There are some alternatives, e.g. we can adjust the bulky regions, change the material.	3	***27***
21	The material we've tested so far ensured us that is very likely to meet this specification.	2	There are a lot of different materials on the market.	1	***4***
26	Our experiences with prototyping suggest that is very likely to meet the specification.	2	We can adjust the size of the frontal openings, gap spacings, or shorten the length. However, the alternatives are less attractive.	4	***32***
34					***0***
35					***0***

Total RPN ***294***

Prioritized List

No.	Specifications Metric	Unit	Accessi-bility Rating (A)	Feasibi-lity Rating (F)	Conting-ency Rating (C)	RPN
11	Unit Manufacturing Cost	US $	5	3	5	***75***
6	Air flow per square meter per time	Meter3/meter2/time	3	5	4	***60***
3	Total Mass	Kilogram	2	4	5	***40***
19	Style (subjective)	Binary	8	5	1	***40***
26	Water vapour transmission rate	Grams/square meter per 24 hours	4	2	4	***32***
20	Wearing volume (former Packing volume)	Meter3	3	3	3	***27***
1	Insulation level (Thermal Resistance range) is adjustable	R-value ((square meters x °C)/watts)	1	2	5	***10***
12	Time required for adjusting insulation level	Seconds	1	2	3	***6***
21	Wind permeability of material (Fraser Air Permeability Test)	CFM	2	2	1	***4***
2	Multiple levels of insulation in one layer					***0***

Pareto Diagram

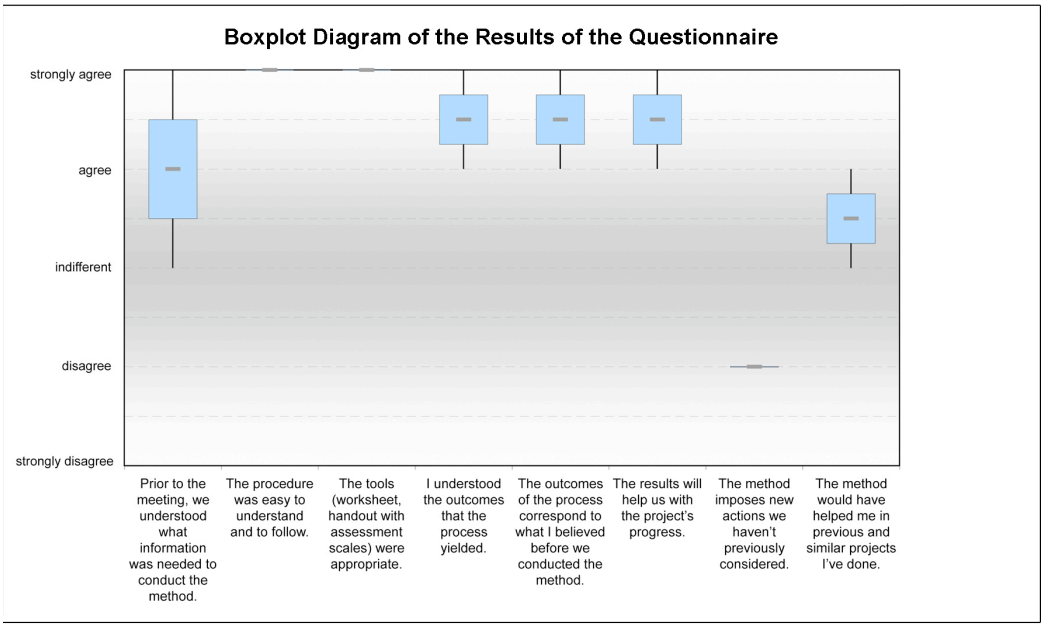


Recommended Actions

No.	Specifications			RPN	Recommended action(s)	Responsibility	Completion Date
	Metric	Unit	... Derived from the Customer Need				
1	Insulation level (Thermal Resistance range) is adjustable	R-value ((square meters x °C)/watts)	adjusts heat loss from the body	***10***			
3	Total Mass	Kilogram	is light-weight	***40***	We should do a first calculation for the weight. And see if we can change material, zippers etc. We need to find out what fabric we should use (in terms of weight) and someone has to to a tradeoff analysis regarding the costs. Because high tech fabric might not be more expensive.	n/a	n/a
6	Air flow per square meter per time	Meter3/meter 2/time	allows ventilation to sweat prone areas of body	***60***	We need to develop a fluid dynamics model and validate that model.	n/a	n/a
11	Unit Manufacturing Cost	US $	is affordable for consumer	***75***	We should come up with a financial model.	We should discuss the responsibility for this task in our next meeting.	Friday, Apr 20th
12	Time required for adjusting insulation level	Seconds	is quick to use	***6***			
19	Style (subjective)	Binary	is stylish and fashionable (is this still applicable?)	***40***	We should do a small survey with sketches to find out what the customer likes.	n/a	n/a
20	***Wearing volume*** (former Packing volume)	Meter3	is stored easily ***wearing volume***	***27***			
21	Wind permeability of material (Fraser Air Permeability Test)	CFM	is wind-resistant/ wind-proof	***4***			
26	Water vapour transmission rate	Grams/square meter per 24 hours	is breathable ***for the whole jacket (not just material)***	***32***	That is correlated to the airflow. When we solve the problems with the air flow, we know a lot more about this specifications.	n/a	n/a

FEEDBACK TEAM "ADJUSTABLE INSULATION JACKET"

					strongly disagree	
Prior to the meeting, we understood what information was needed to conduct the method.	1	0	1	0	0	Σ 2
The procedure was easy to understand and to follow.	2	0	0	0	0	Σ 2
The tools (worksheet, handout with assessment scales) were appropriate.	2	0	0	0	0	Σ 2
I understood the outcomes that the process yielded.	2	0	0	0	0	Σ 2
The outcomes of the process correspond to what I believed before we conducted the method.	1	1	0	0	0	Σ 2
The results will help us with the project's progress.	1	1	0	0	0	Σ 2
The method imposes new actions we haven't previously considers.	0	0	0	2	0	Σ 2
The method would have helped me in previous and similar projects I've done.	0	1	1	0	0	Σ 2



9.4.7 Results of the Feedback Questionnaire

For each of the feedback questions, the following figure presents the ratings of each team and in total.